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Ho et al.

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(54) **PATIENT INTERFACE ASSEMBLY AND SYSTEM USING SAME**

(75) Inventors: **Peter Chi Fai Ho**, Pittsburgh, PA (US);
Jerome Matula, Jr., Apollo, PA (US);
Richard J. Lordo, Butler, PA (US);
Lance Busch, Trafford, PA (US);
Derrick Andrews, Markleton, PA (US);
Luke Stonis, Columbus, OH (US);
Chris Von Dohlen, St. Louis Park, MN (US)

(73) Assignee: **RIC Investments, LLC**, Wilmington, DE (US)

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A62B 18/02 (2006.01)

(52) **U.S. Cl.**
USPC **128/207.13; 128/206.21; 128/206.24**

(58) **Field of Classification Search**
USPC 128/202.27, 205.25, 206.12, 206.24, 128/206.27, 206.28, 207.11, 207.12
See application file for complete search history.

(56) **References Cited**
U.S. PATENT DOCUMENTS
601,401 A * 3/1898 Praeckel 128/206.16
853,439 A 5/1907 Clark
1,081,745 A 12/1913 Johnston
1,323,217 A 11/1919 Darrow
2,011,733 A * 8/1935 Shindel 128/206.24
2,079,581 A * 5/1937 Whipple 128/206.24
2,079,582 A * 5/1937 Whipple 128/206.24

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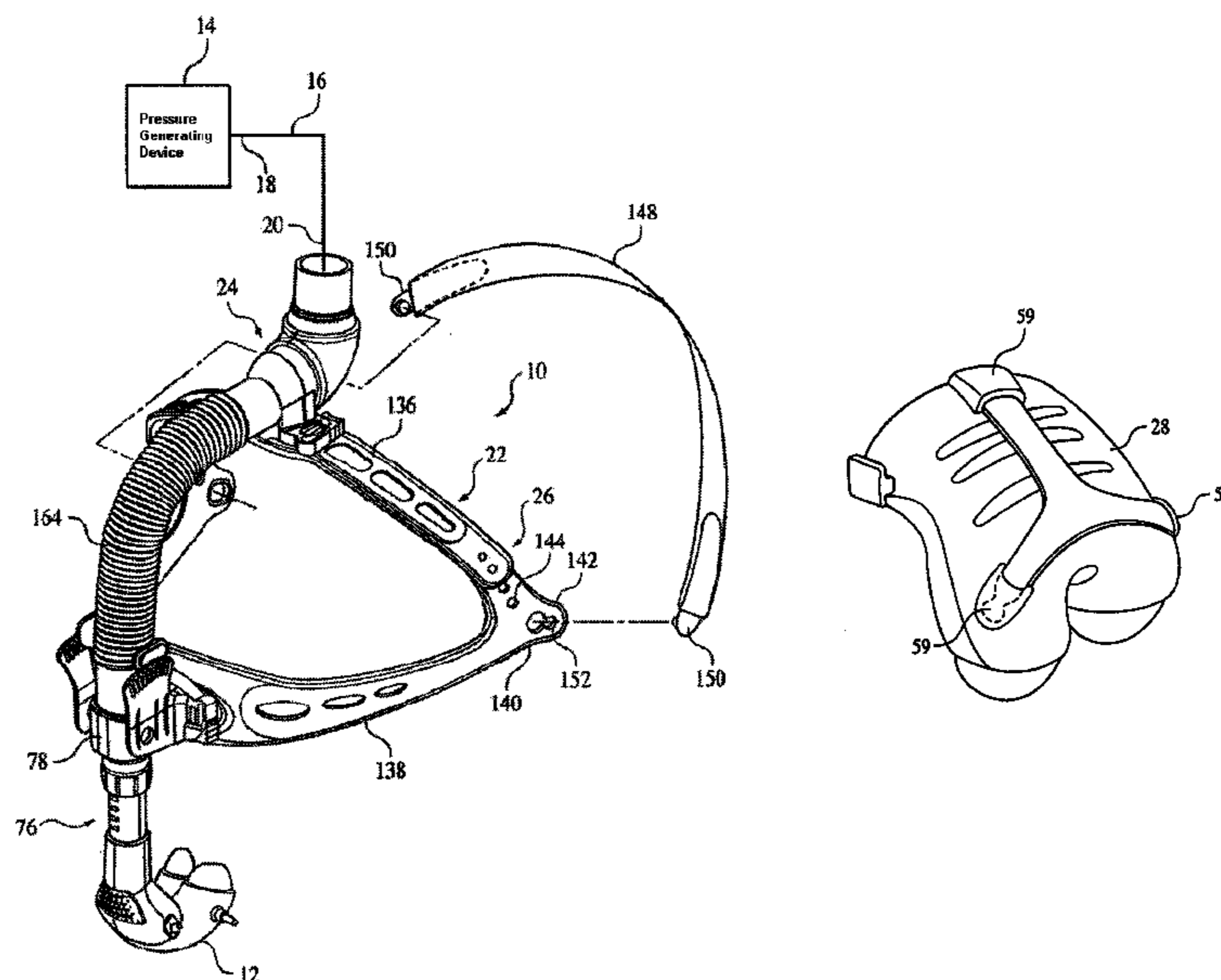
FOREIGN PATENT DOCUMENTS
WO WO 9943375 A1 * 9/1999
WO WO 0074758 A1 12/2000
WO WO 0100266 A2 1/2001
WO WO 02096342 A2 12/2002

OTHER PUBLICATIONS
Website, "Breeze DreamSeal", 1 page, Dec. 11, 2003.
Website, "ADAM circuit (nasal pillows)", 3 pages, Dec. 11, 2003.

Primary Examiner — Justine Yu
Assistant Examiner — LaToya M Louis
(74) *Attorney, Agent, or Firm* — Michael W. Haas

(57) **ABSTRACT**
A patient interface assembly that includes a patient interface device, a headgear, and pivoting coupling member joining the interface device to a headgear assembly. In one embodiment, the patient interface device is a nasal cushion that includes a formable support mounted to the nasal cushion for providing support and adjustment of the nasal cushion to improve fit and comfort. In a further embodiment, a pair of rigid connecting members couple the patient interface device to the headgear.

4 Claims, 25 Drawing Sheets



(56)

References Cited

U.S. PATENT DOCUMENTS

2,259,817 A 10/1941 Hawkins
 2,323,199 A * 6/1943 Bulbulian 128/206.24
 2,818,067 A 12/1957 Issaiewitch
 3,040,741 A * 6/1962 Carolan 128/206.27
 3,056,402 A * 10/1962 Dickinson 128/206.27
 3,092,105 A * 6/1963 Gabb 128/206.27
 3,379,195 A * 4/1968 Bleach 128/205.25
 3,416,521 A * 12/1968 Hamlin 128/207.11
 3,850,168 A * 11/1974 Ferguson et al. 128/206.27
 3,978,854 A 9/1976 Mills, Jr.
 4,354,488 A 10/1982 Bartos
 4,367,735 A 1/1983 Dali
 4,782,832 A 11/1988 Trimble
 4,808,160 A 2/1989 Timmons
 4,919,128 A 4/1990 Kopala
 4,938,209 A 7/1990 Fry
 5,042,478 A 8/1991 Kopala
 5,069,205 A 12/1991 Urso
 5,181,507 A 1/1993 Michel
 5,269,296 A 12/1993 Landis
 5,477,852 A 12/1995 Landis
 5,517,986 A 5/1996 Starr
 5,533,506 A 7/1996 Wood
 5,538,000 A 7/1996 Rudolph

5,558,089 A 9/1996 Castiglione
 5,724,965 A 3/1998 Handke
 5,752,510 A 5/1998 Goldstein
 5,921,239 A 7/1999 McAll
 6,012,455 A 1/2000 Goldstein
 6,019,101 A 2/2000 Cotner
 6,119,693 A 9/2000 Kwok
 6,119,694 A 9/2000 Correa
 6,347,631 B1 2/2002 Hansen
 6,431,171 B1 8/2002 Burton
 6,463,931 B1 10/2002 Kwok
 6,497,232 B2 12/2002 Fecteau
 6,516,802 B2 2/2003 Hansen
 6,520,182 B1 2/2003 Gunaratnam
 6,532,961 B1 3/2003 Kwok
 6,561,191 B1 5/2003 Kwok
 6,581,594 B1 6/2003 Drew
 6,595,214 B1 7/2003 Hecker
 6,662,803 B2 12/2003 Gradon
 6,712,072 B1 3/2004 Lang
 6,851,428 B2 2/2005 Dennis
 6,854,465 B2 2/2005 Bordwick
 2001/0042547 A1 * 11/2001 McDonald et al. 128/207.11
 2002/0104540 A1 8/2002 Kwok
 2002/0134388 A1 * 9/2002 Chang 128/206.21
 2003/0075180 A1 4/2003 Raje

* cited by examiner

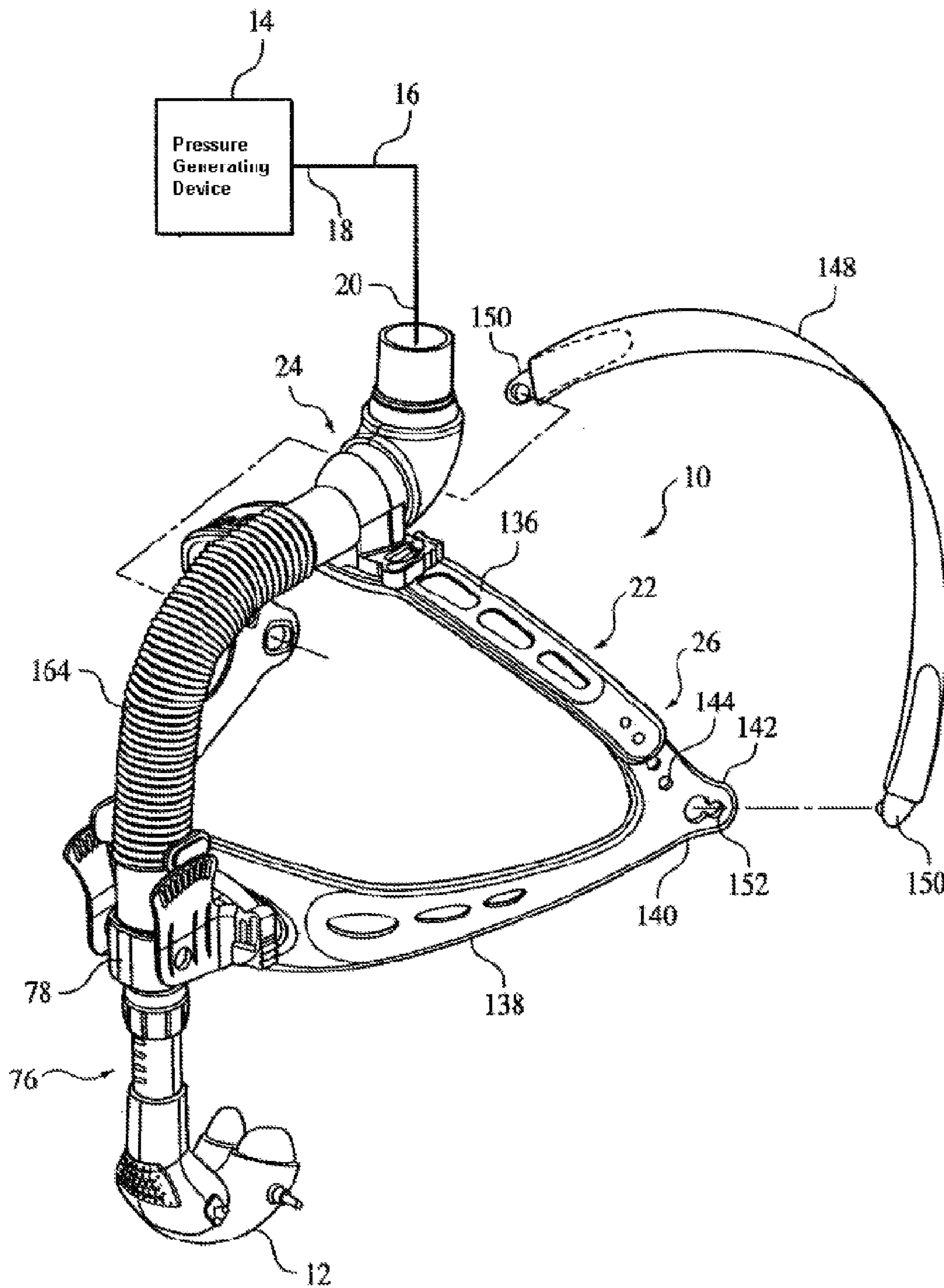


FIGURE 1

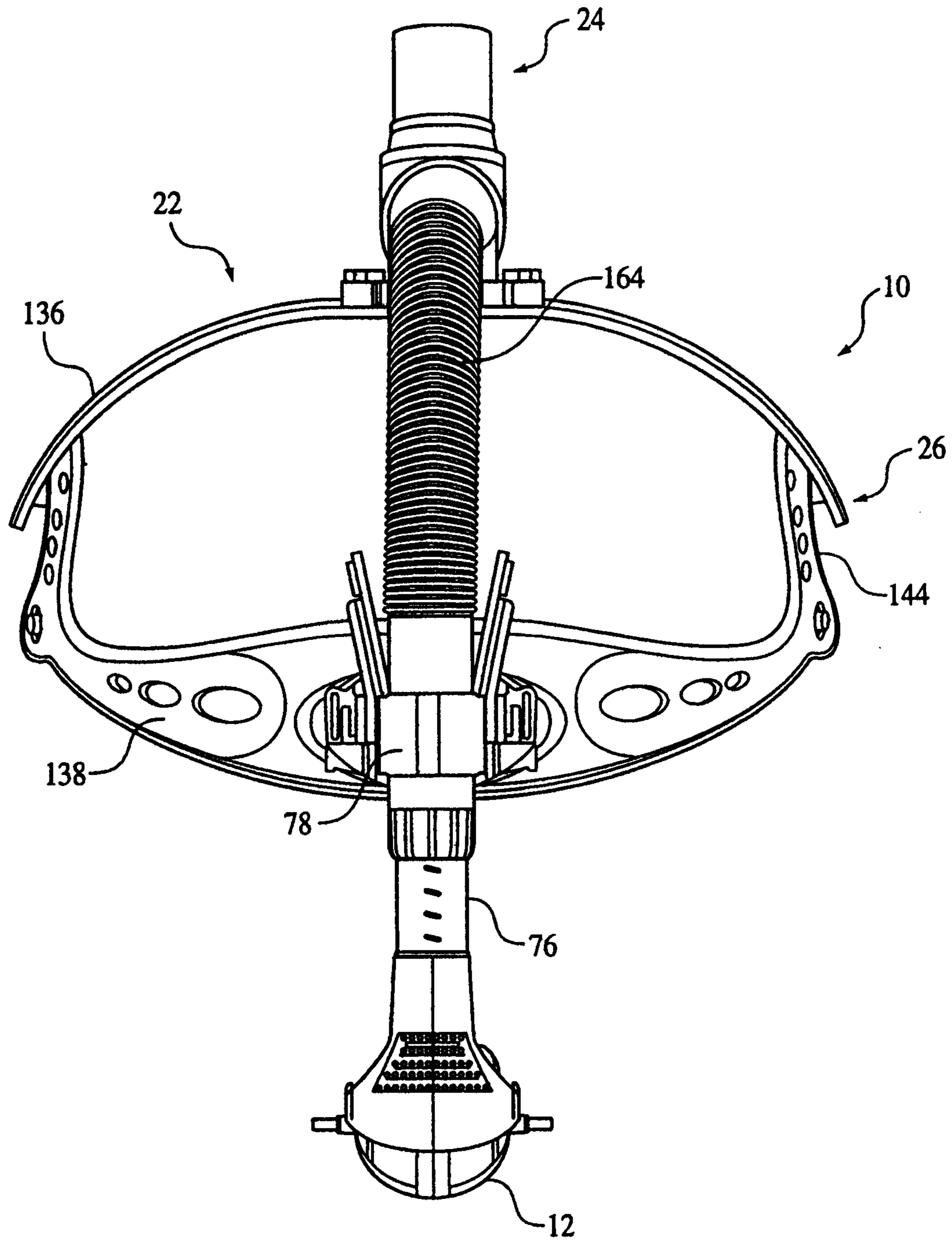


FIG. 2

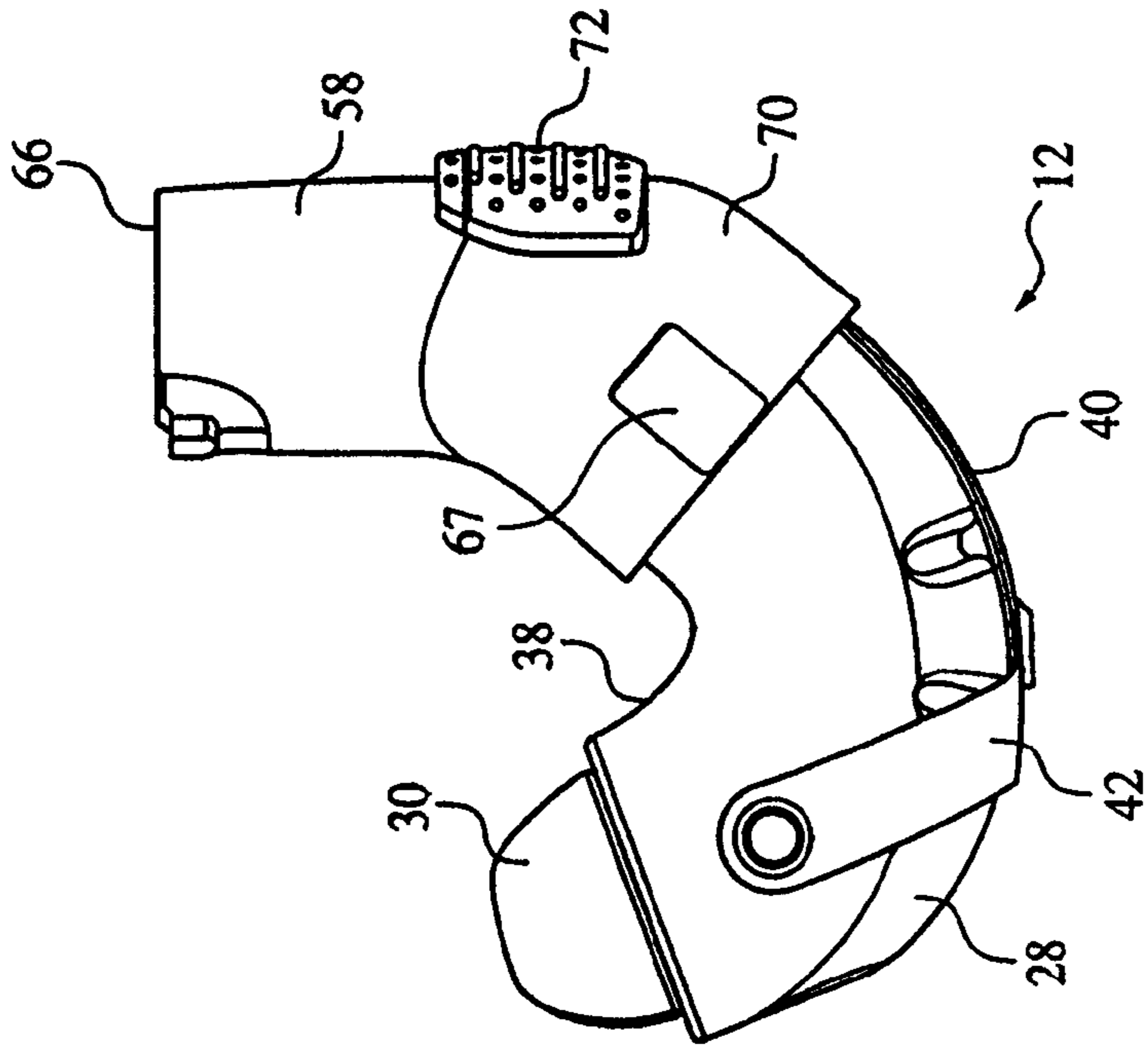


FIG. 4

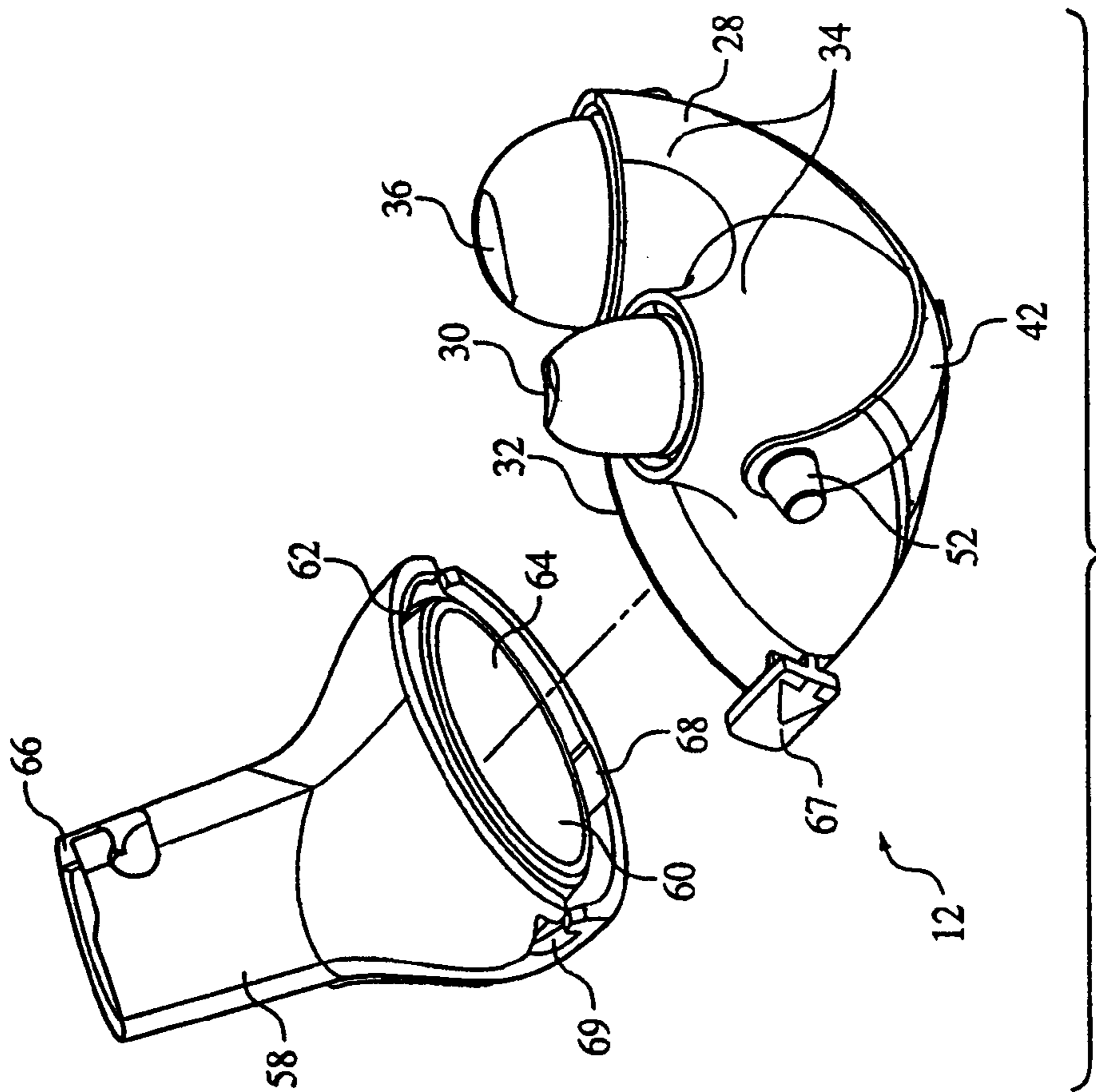


FIG. 3

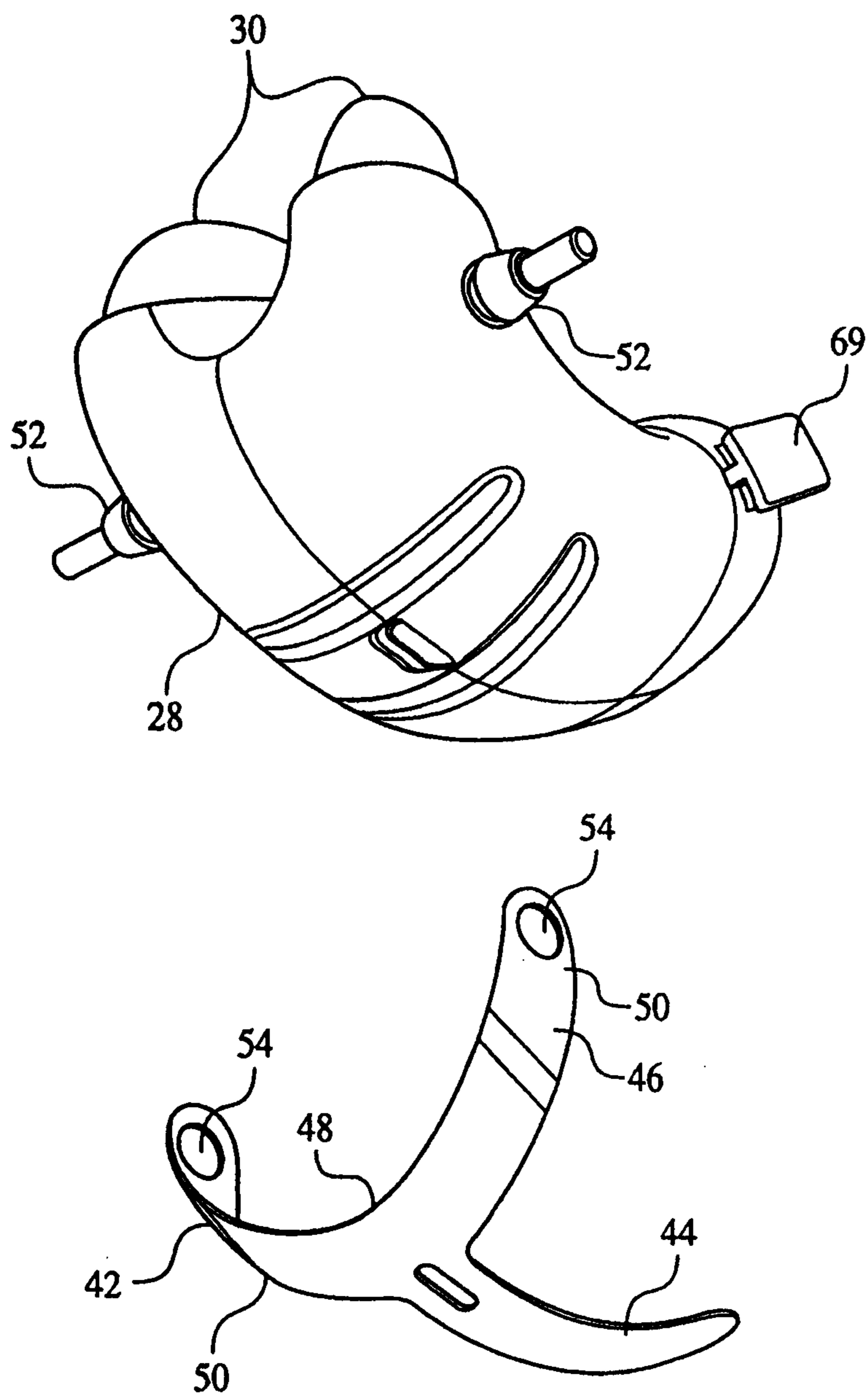


FIG. 5

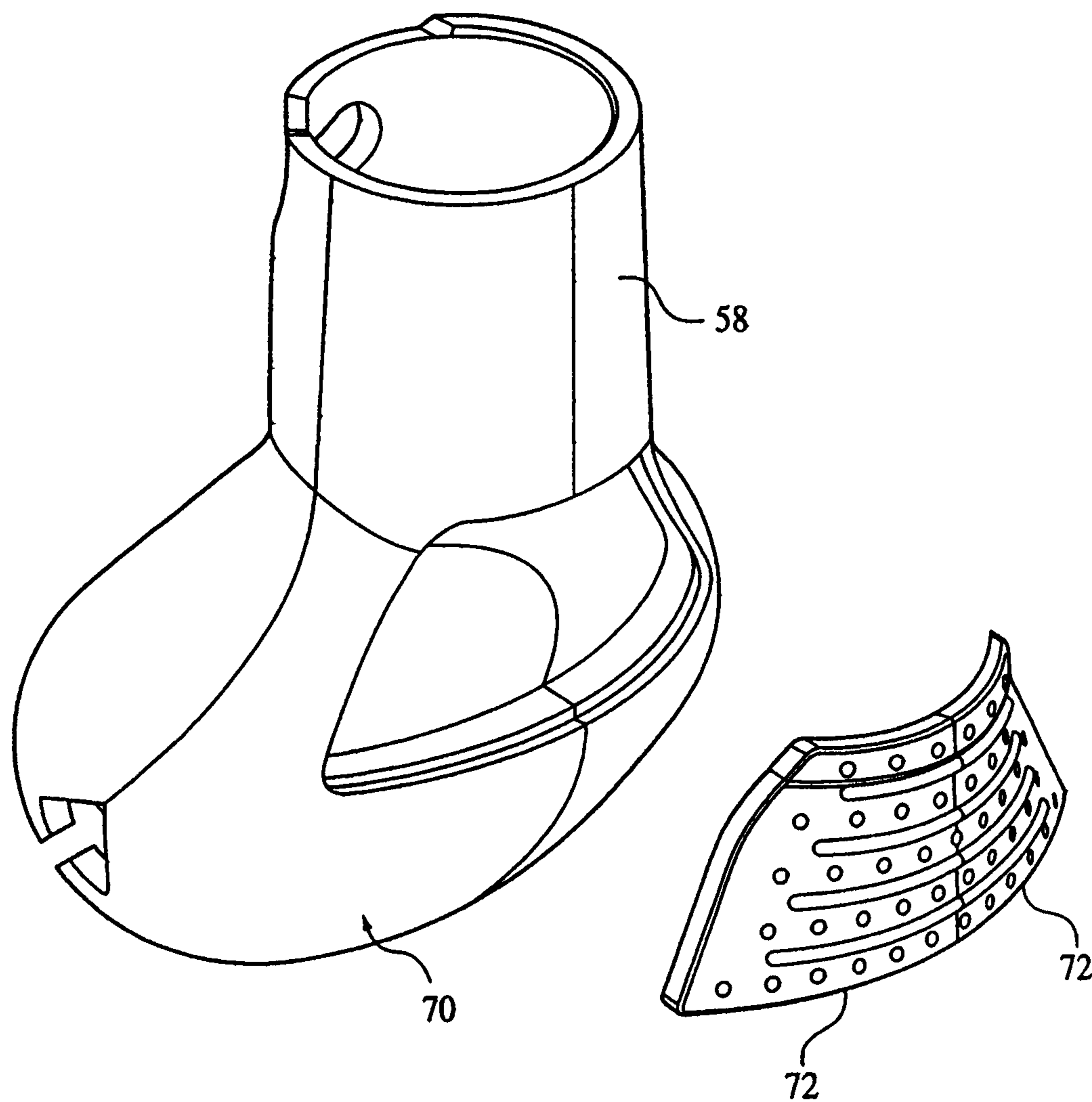


FIG. 6

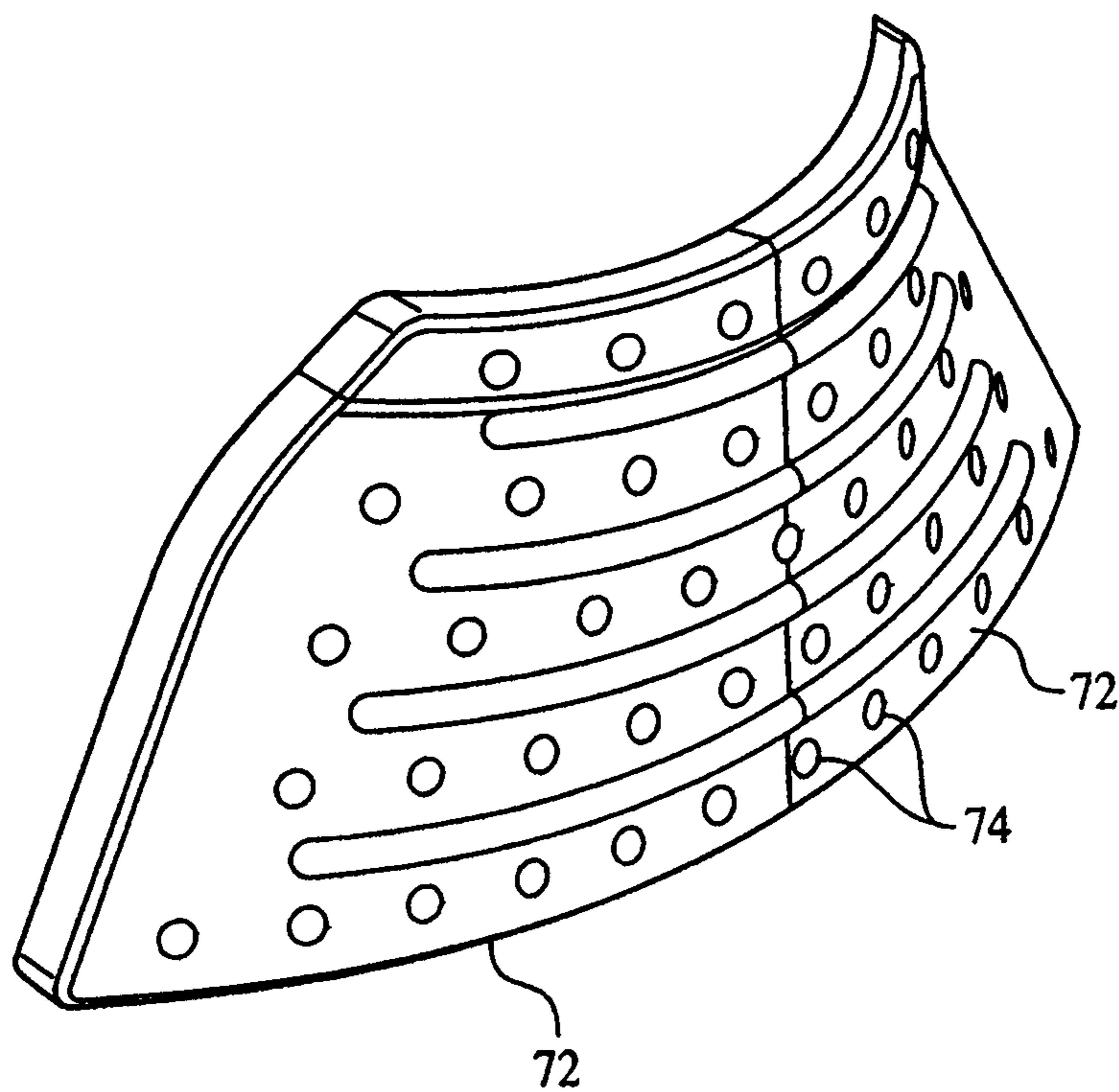


FIG. 7

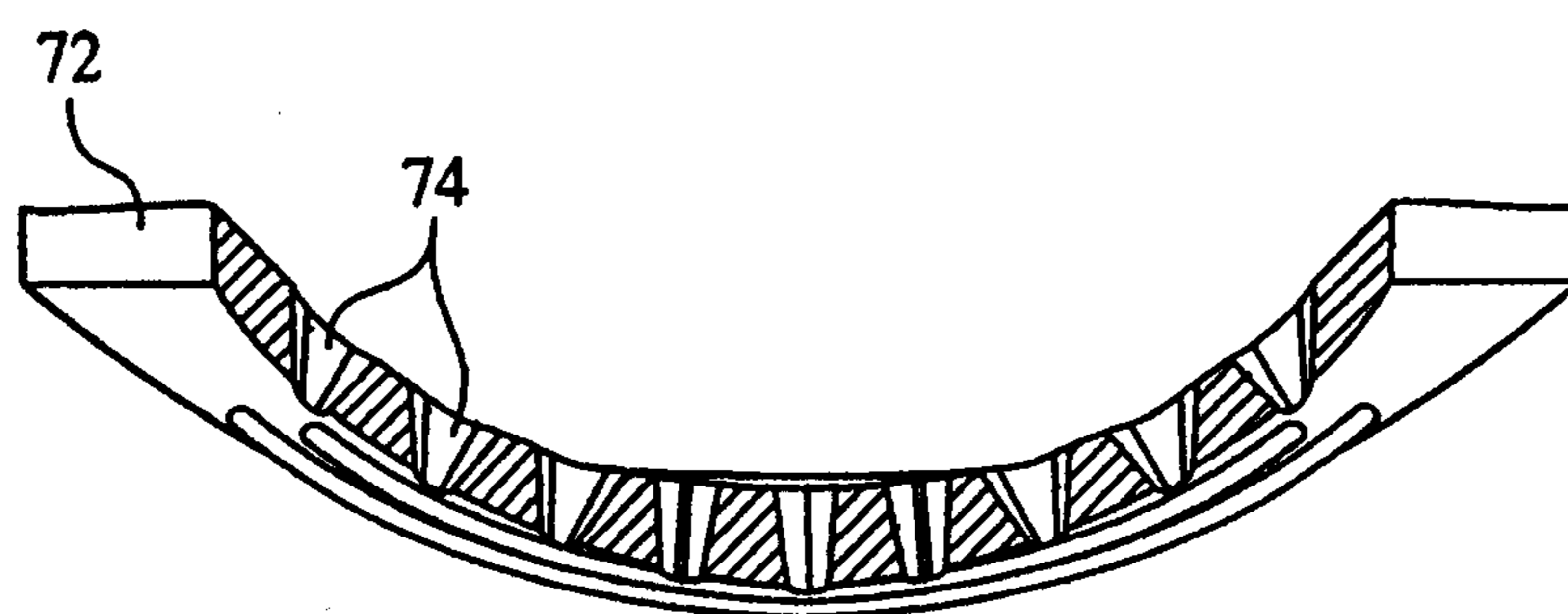


FIG. 8

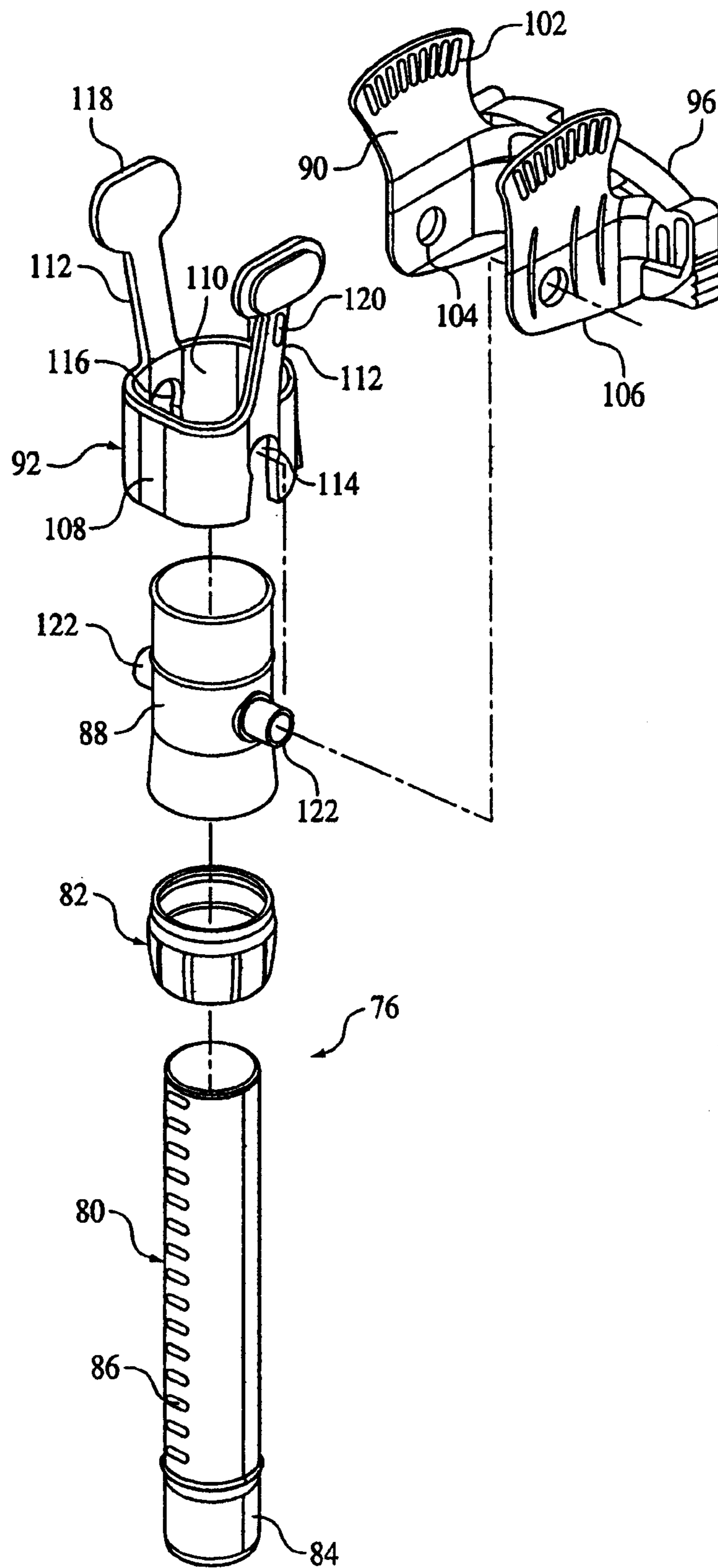


FIG. 9

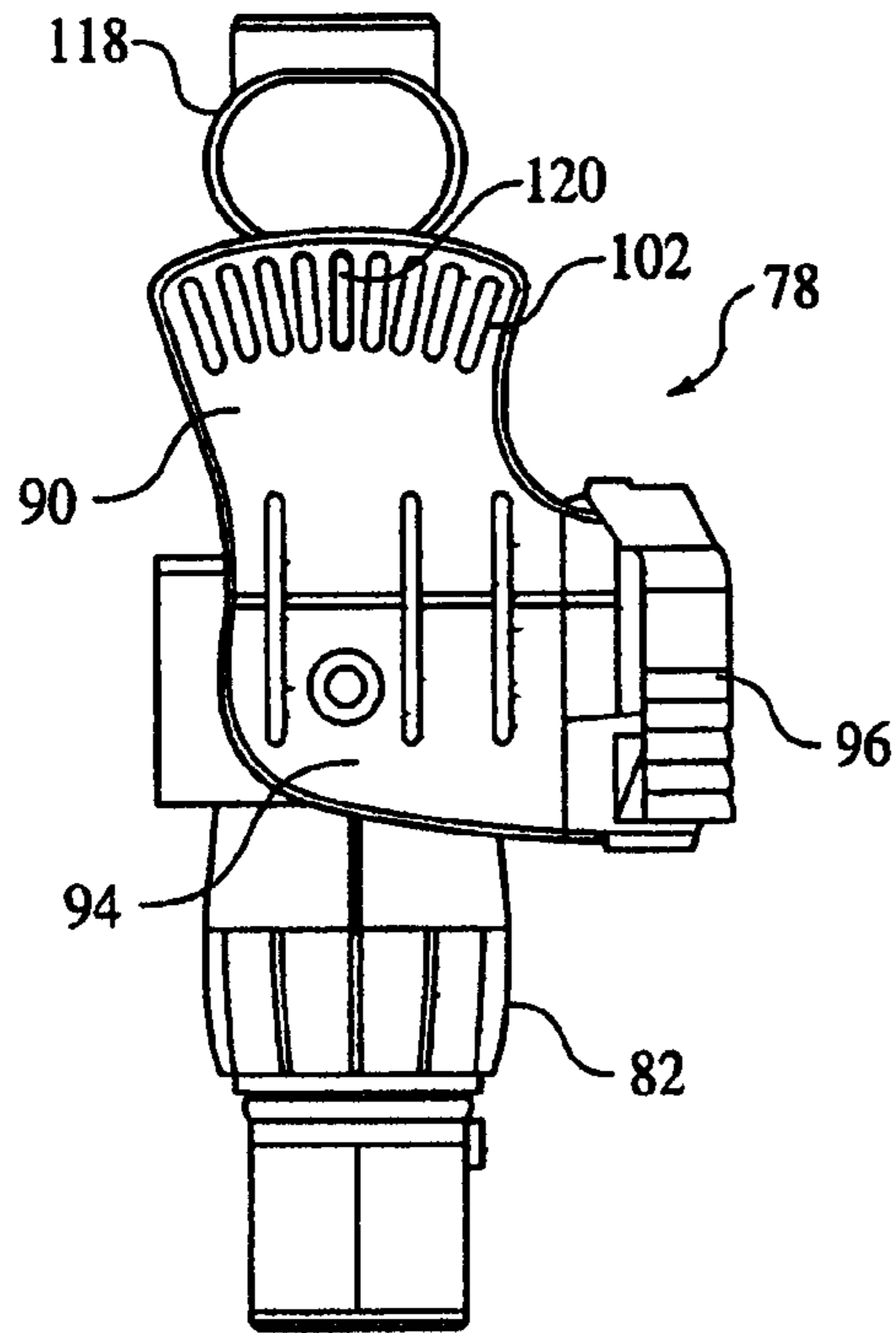


FIG. 10

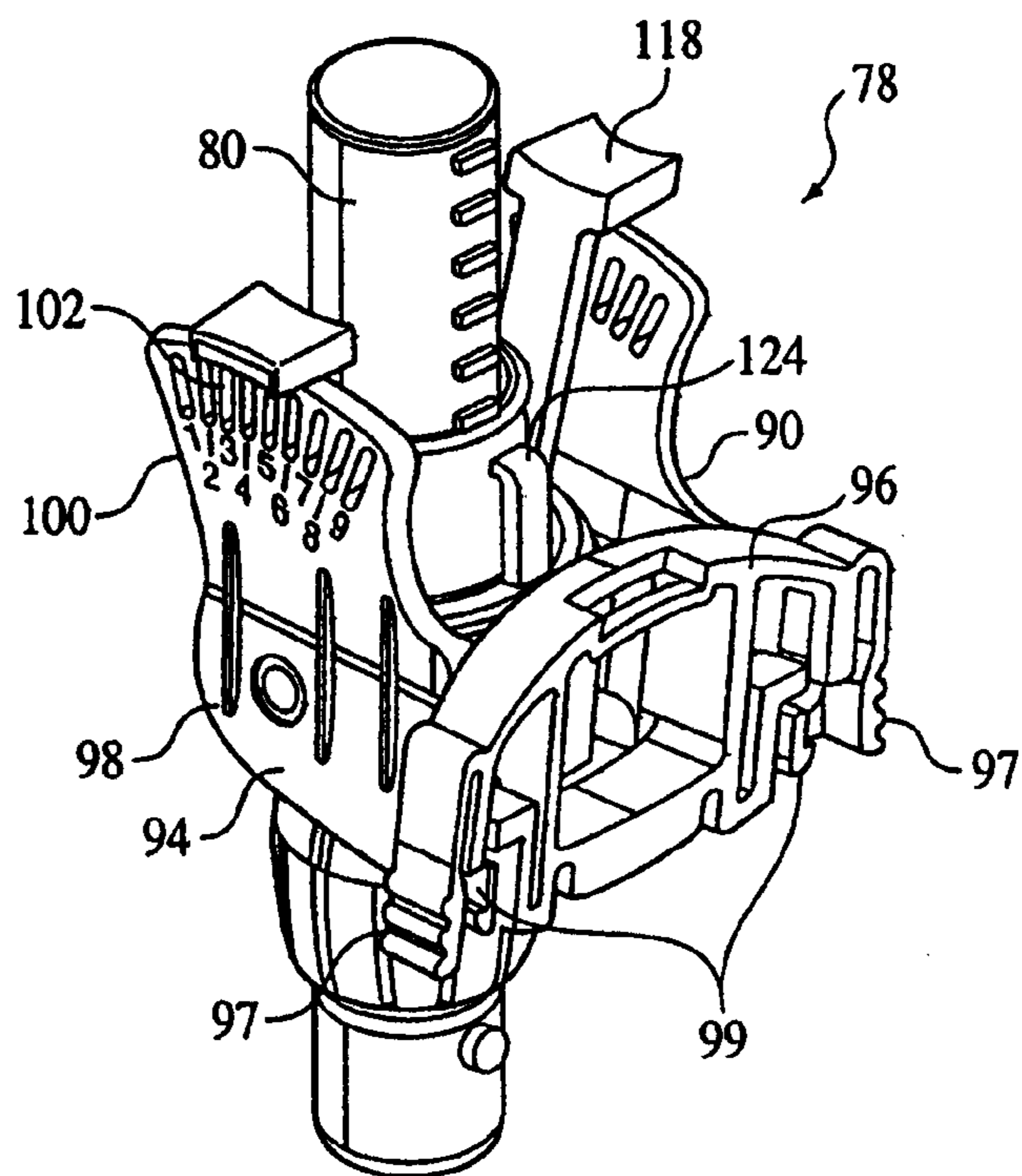


FIG. 11

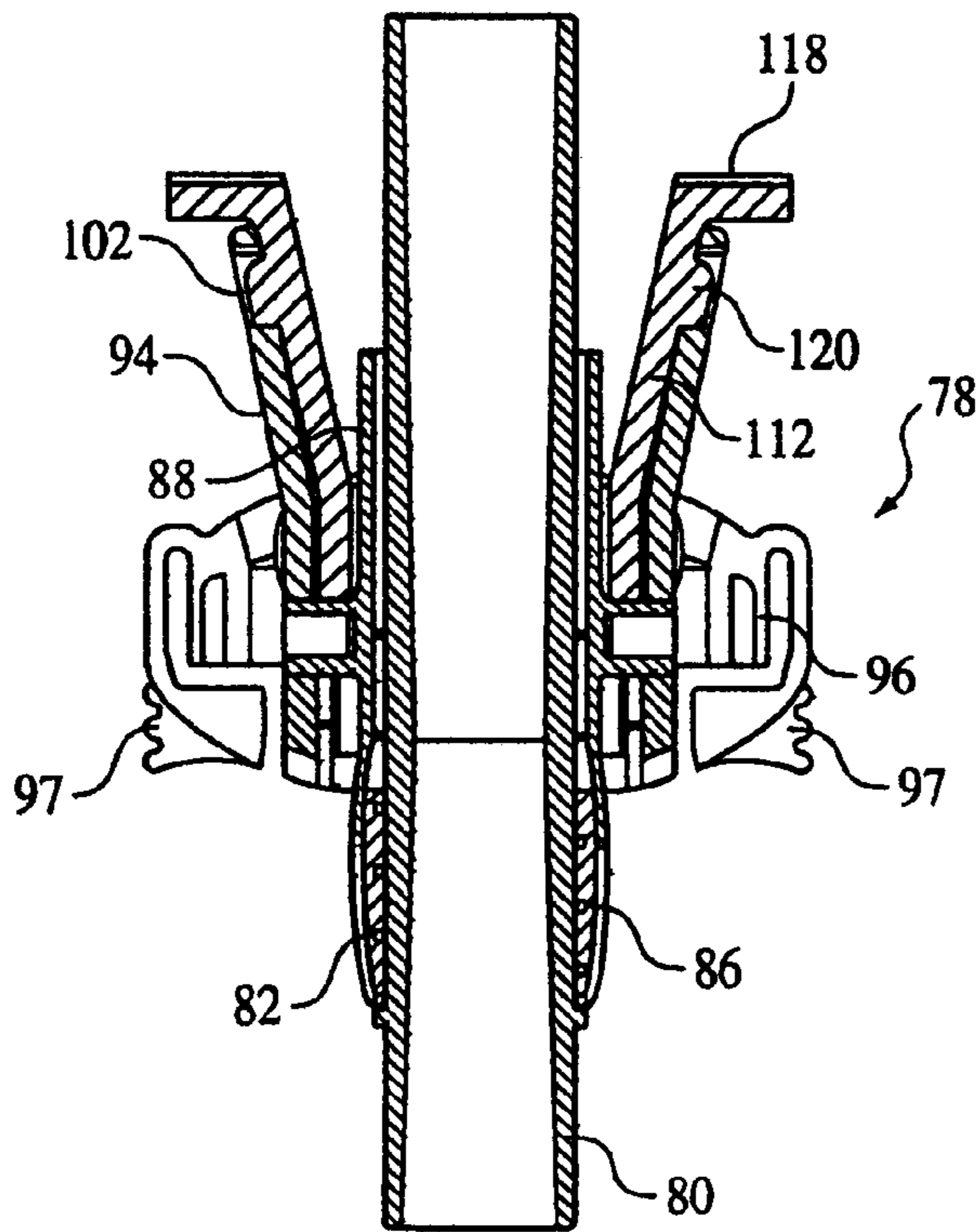


FIG. 12

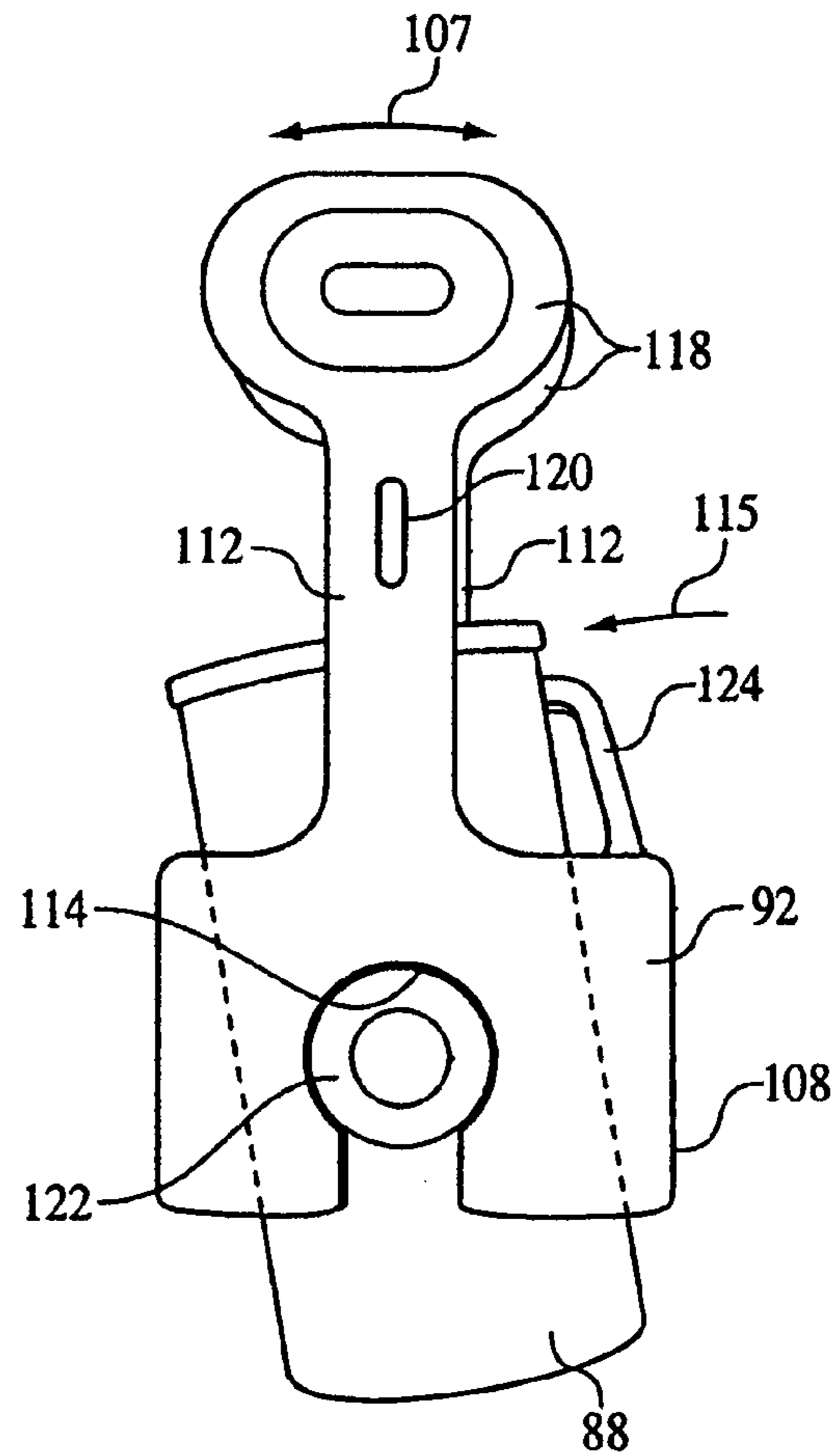


FIG. 13

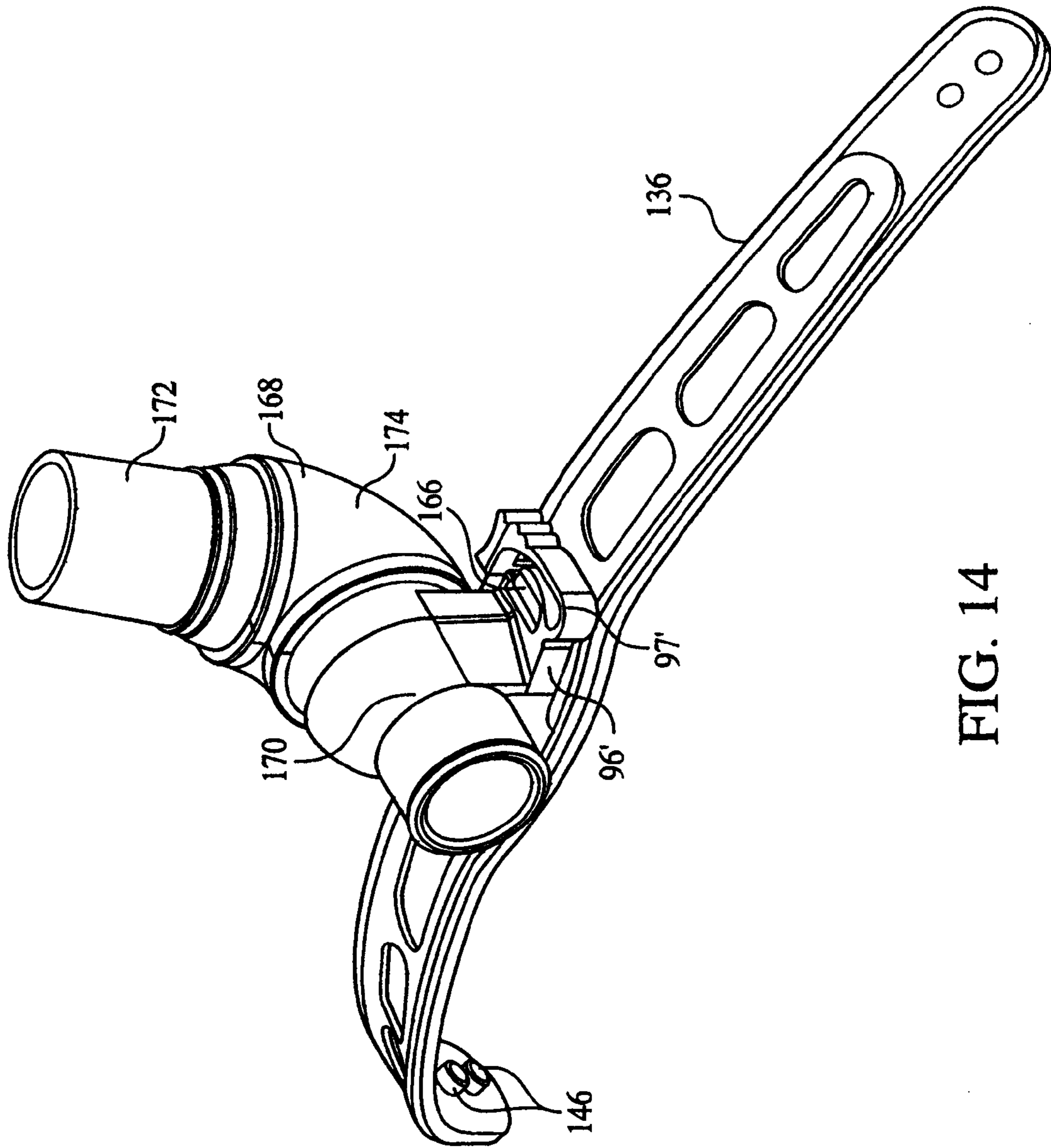


FIG. 14

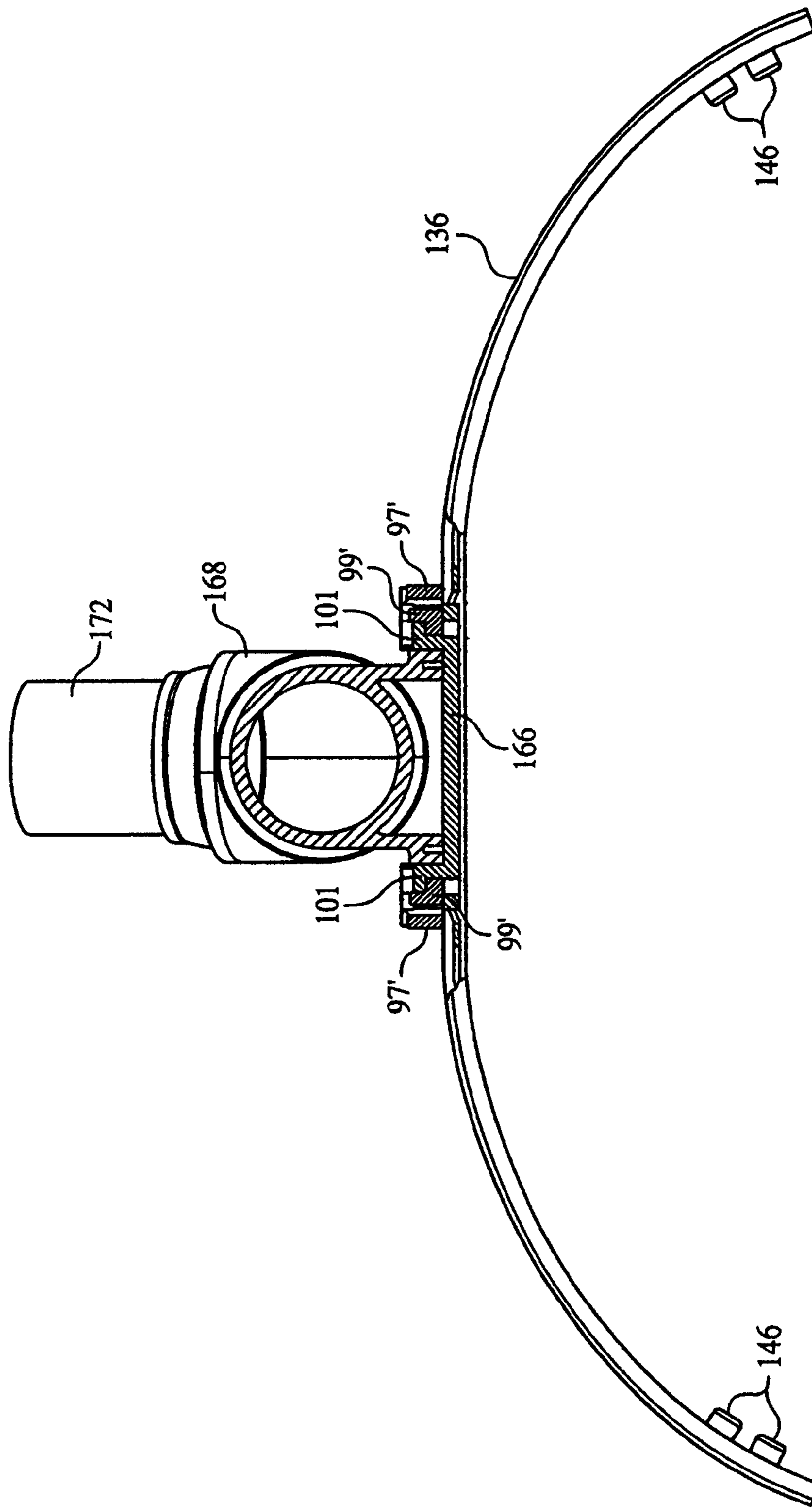


FIG. 15

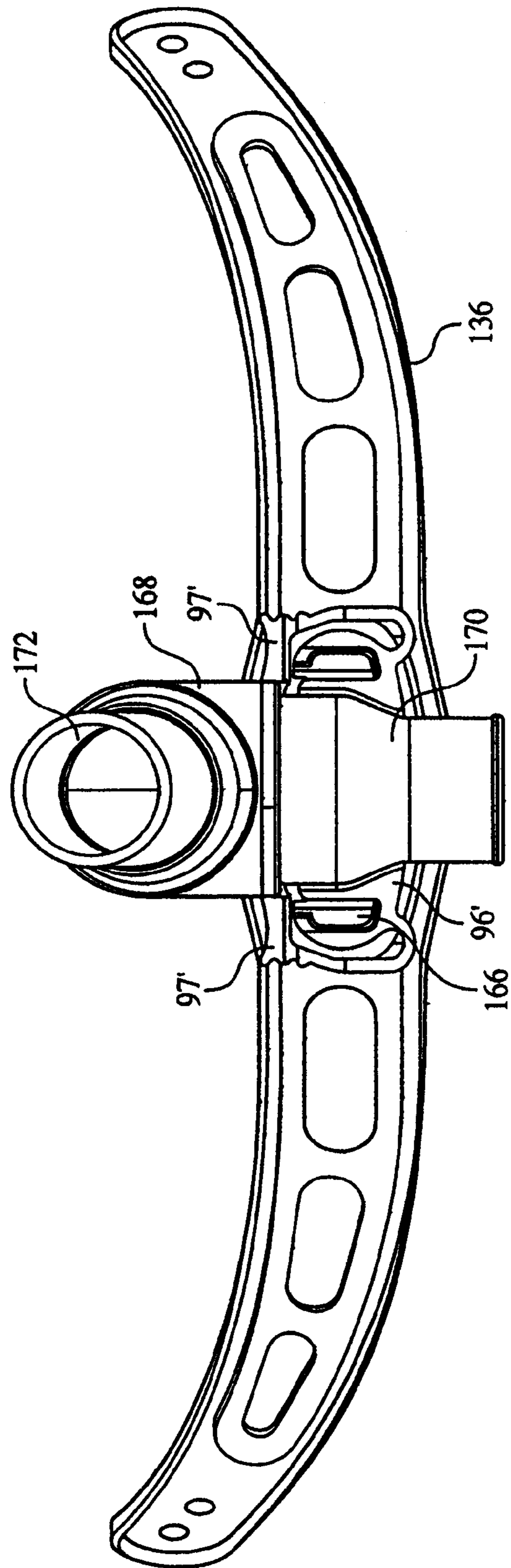


FIG. 16

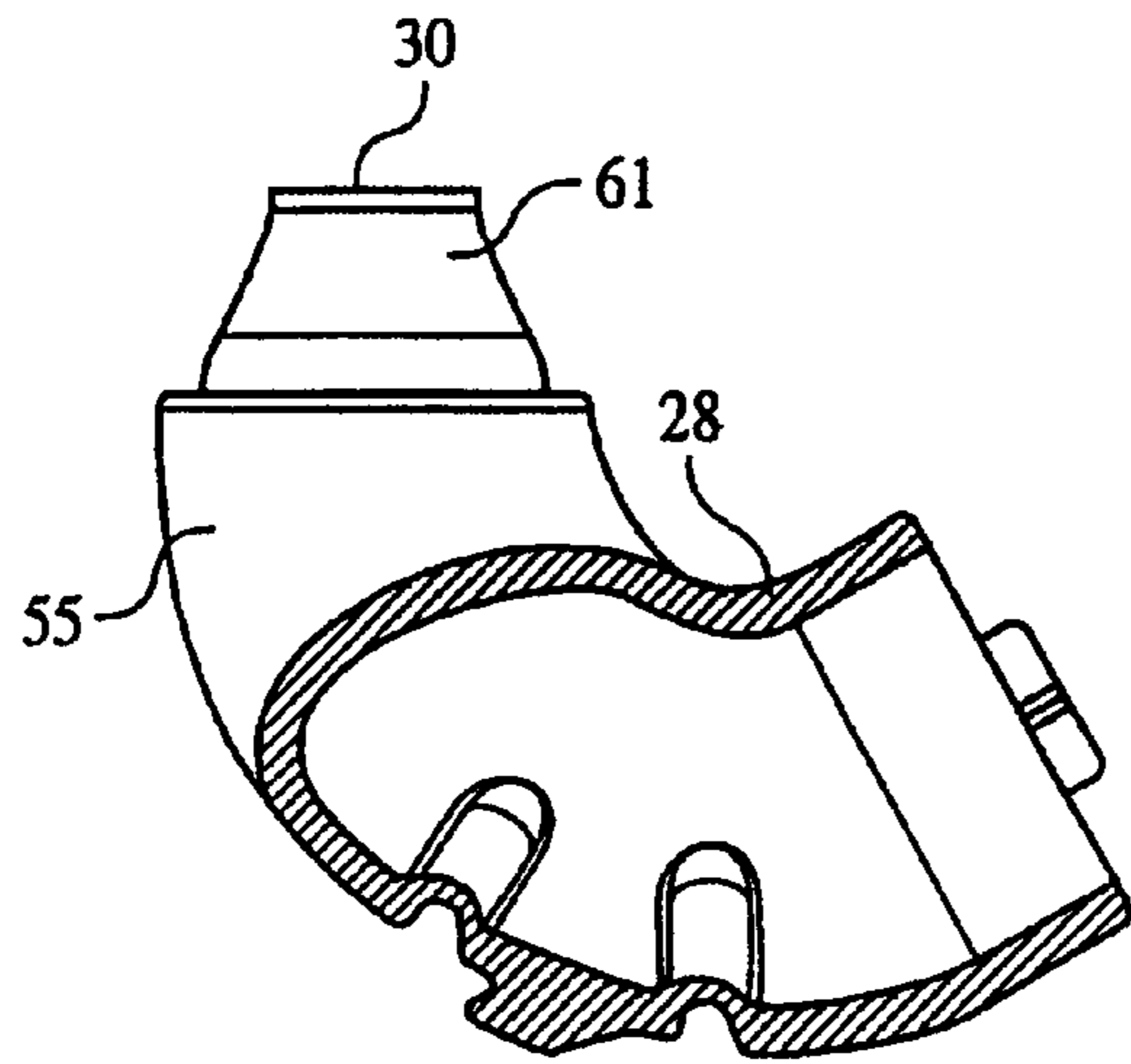


FIG. 17A

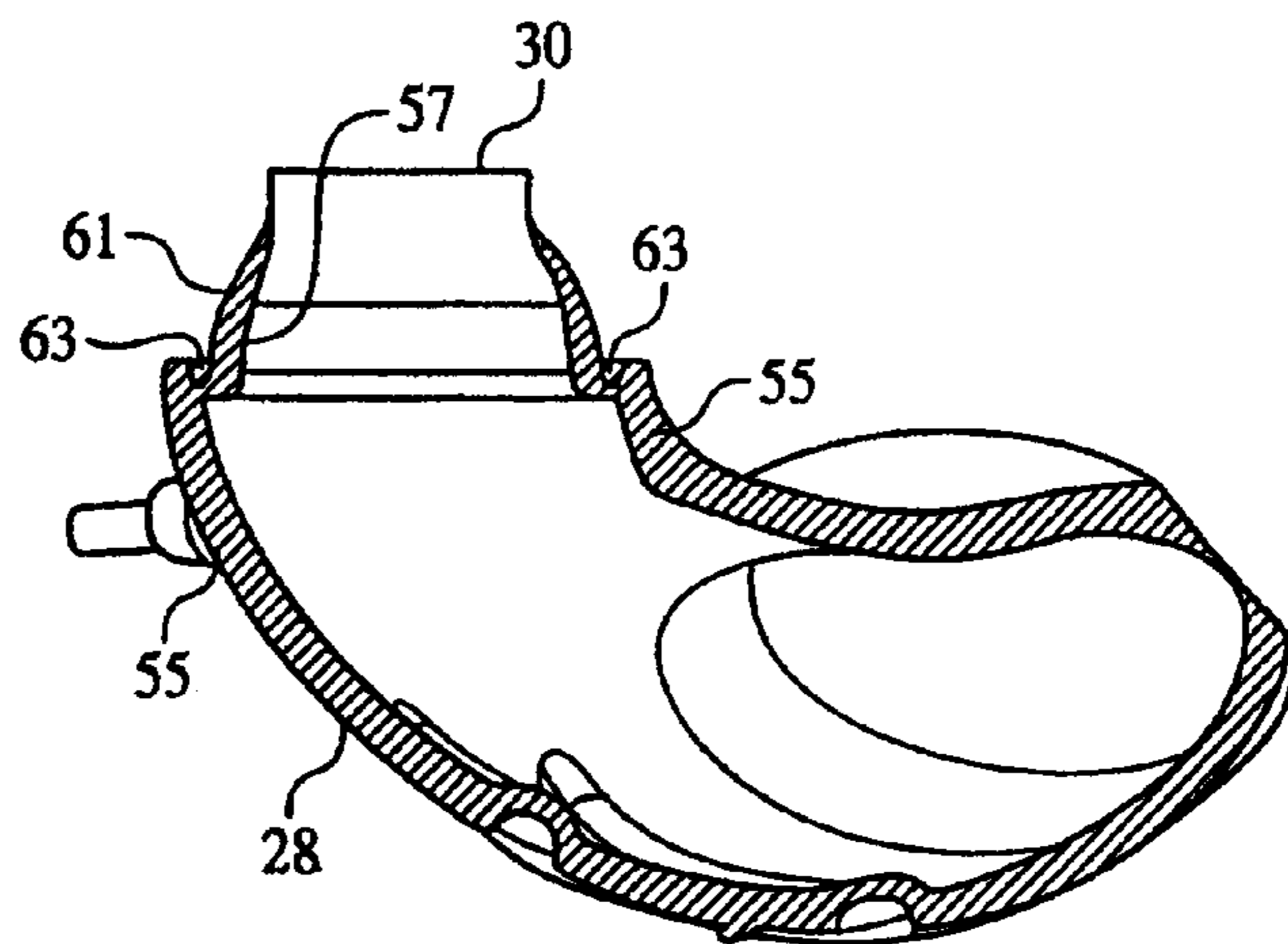


FIG. 17B

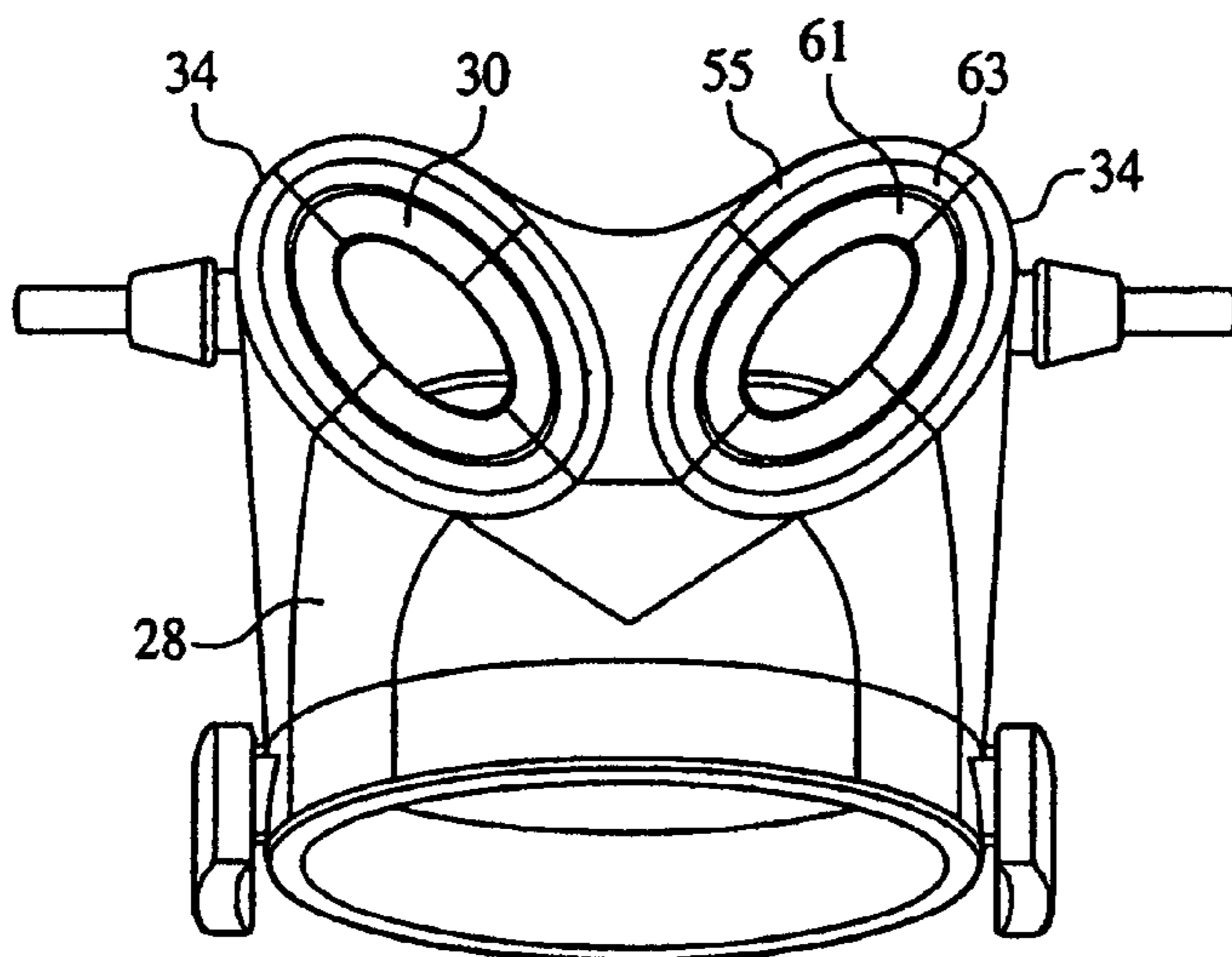


FIG. 17C

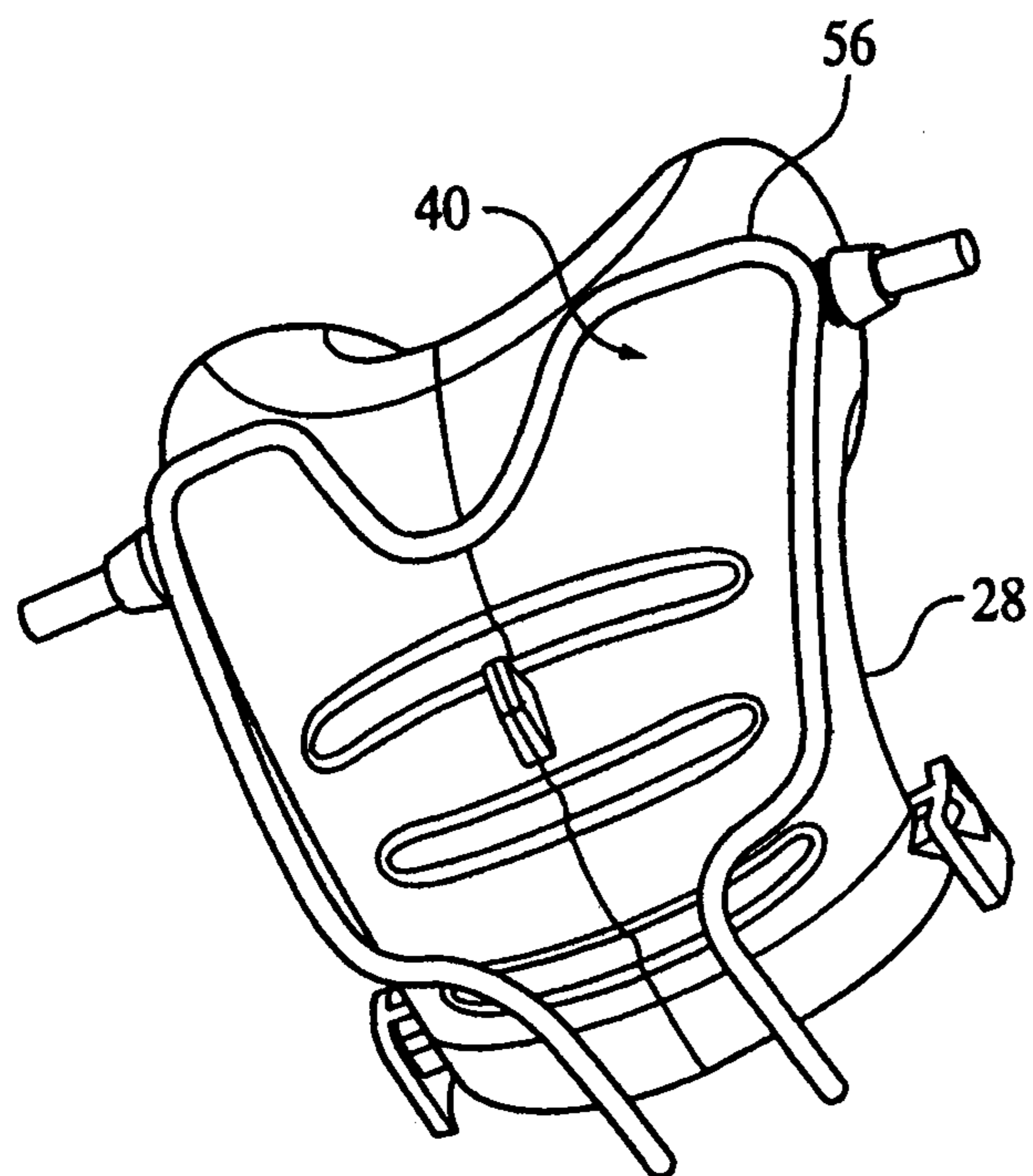


FIG. 18

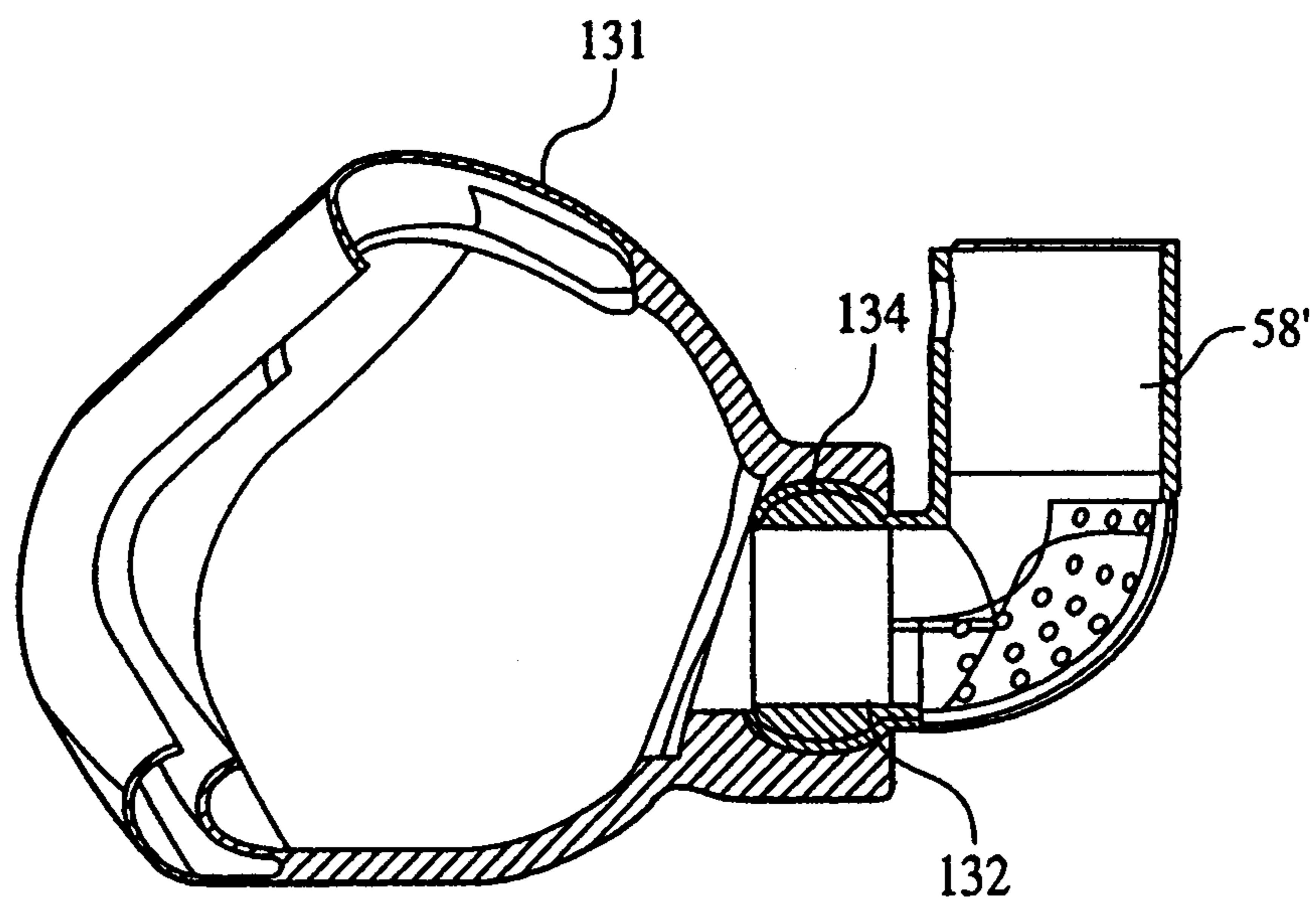


FIG. 20

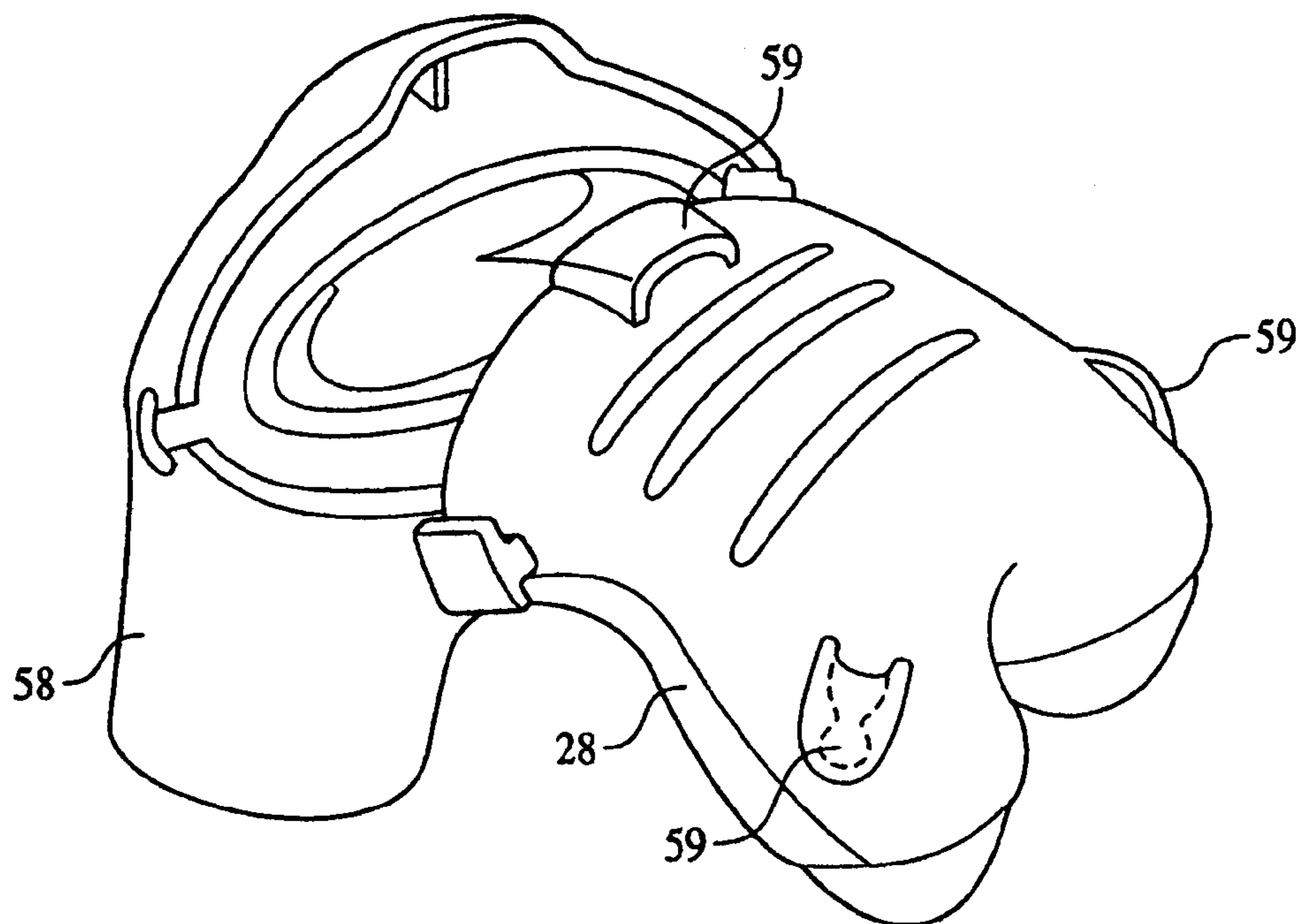


FIG. 19A

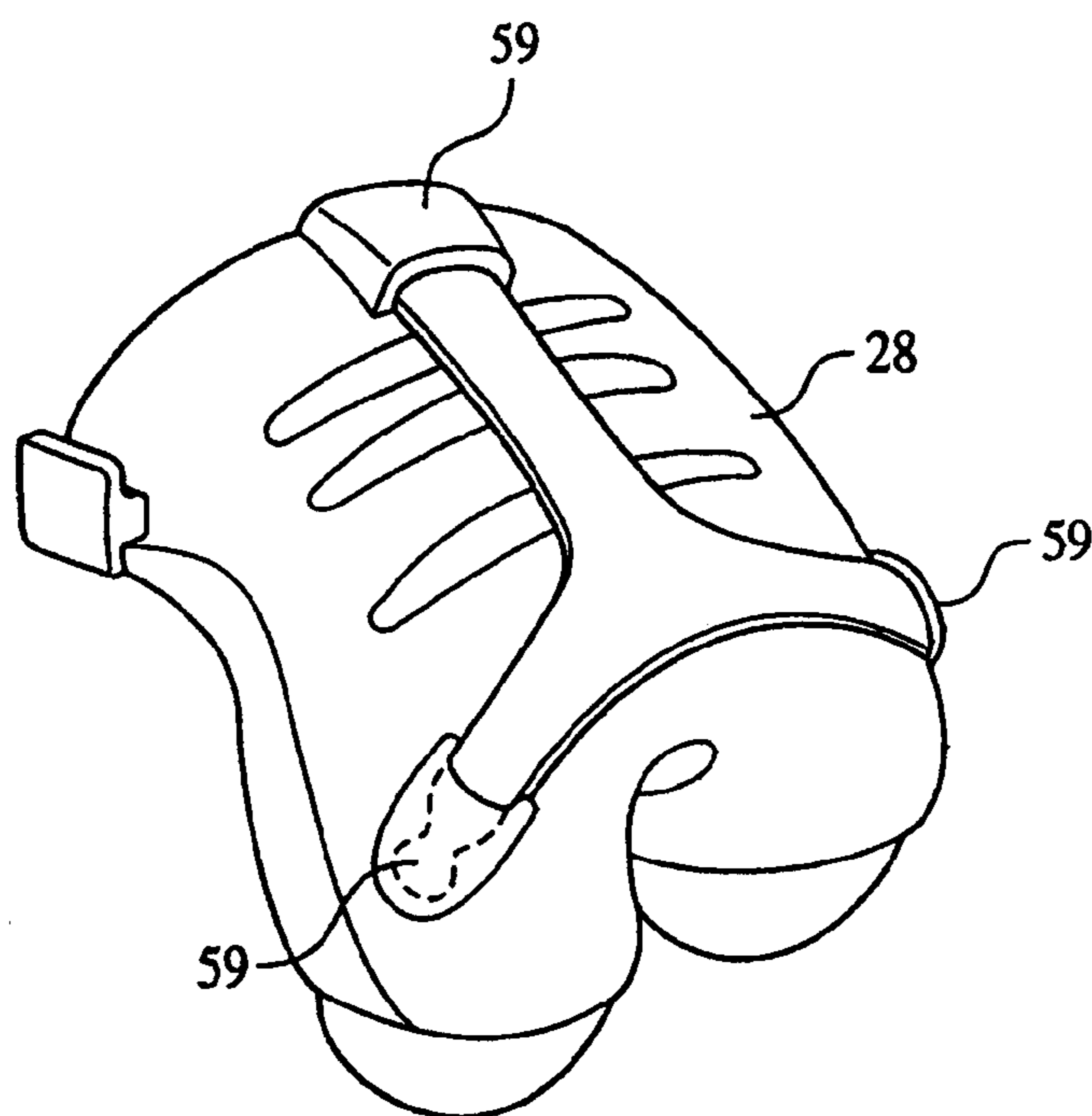


FIG. 19B

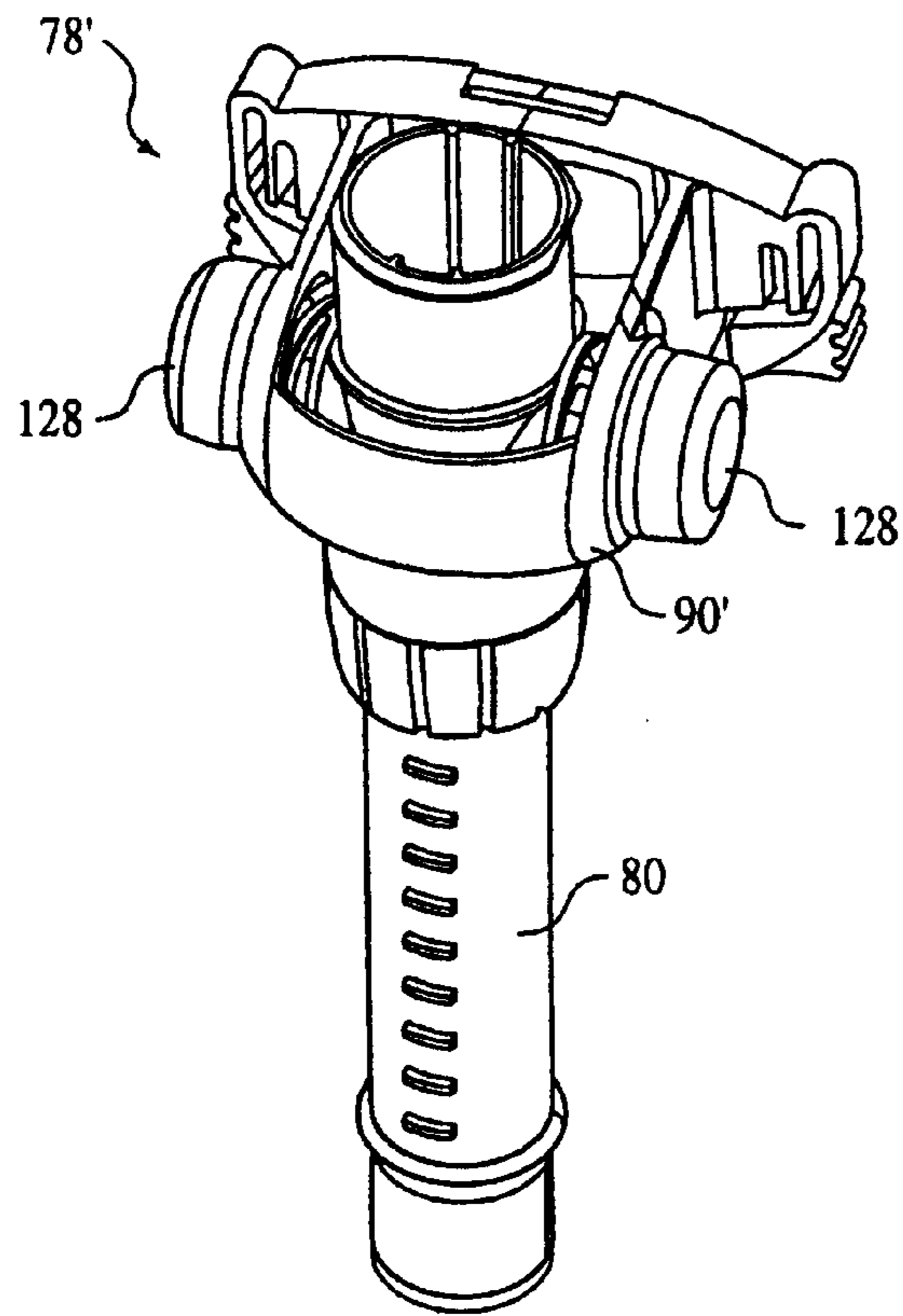


FIG. 21A

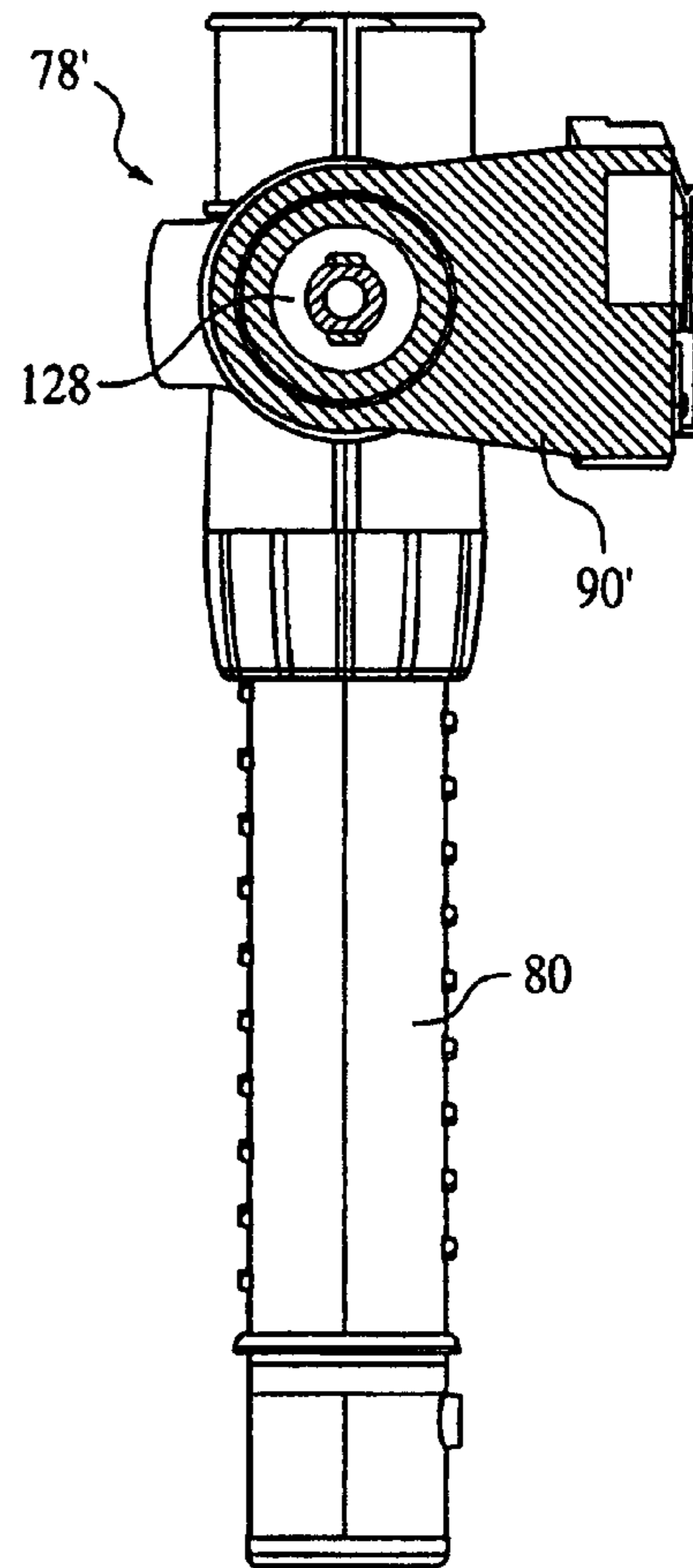


FIG. 21B

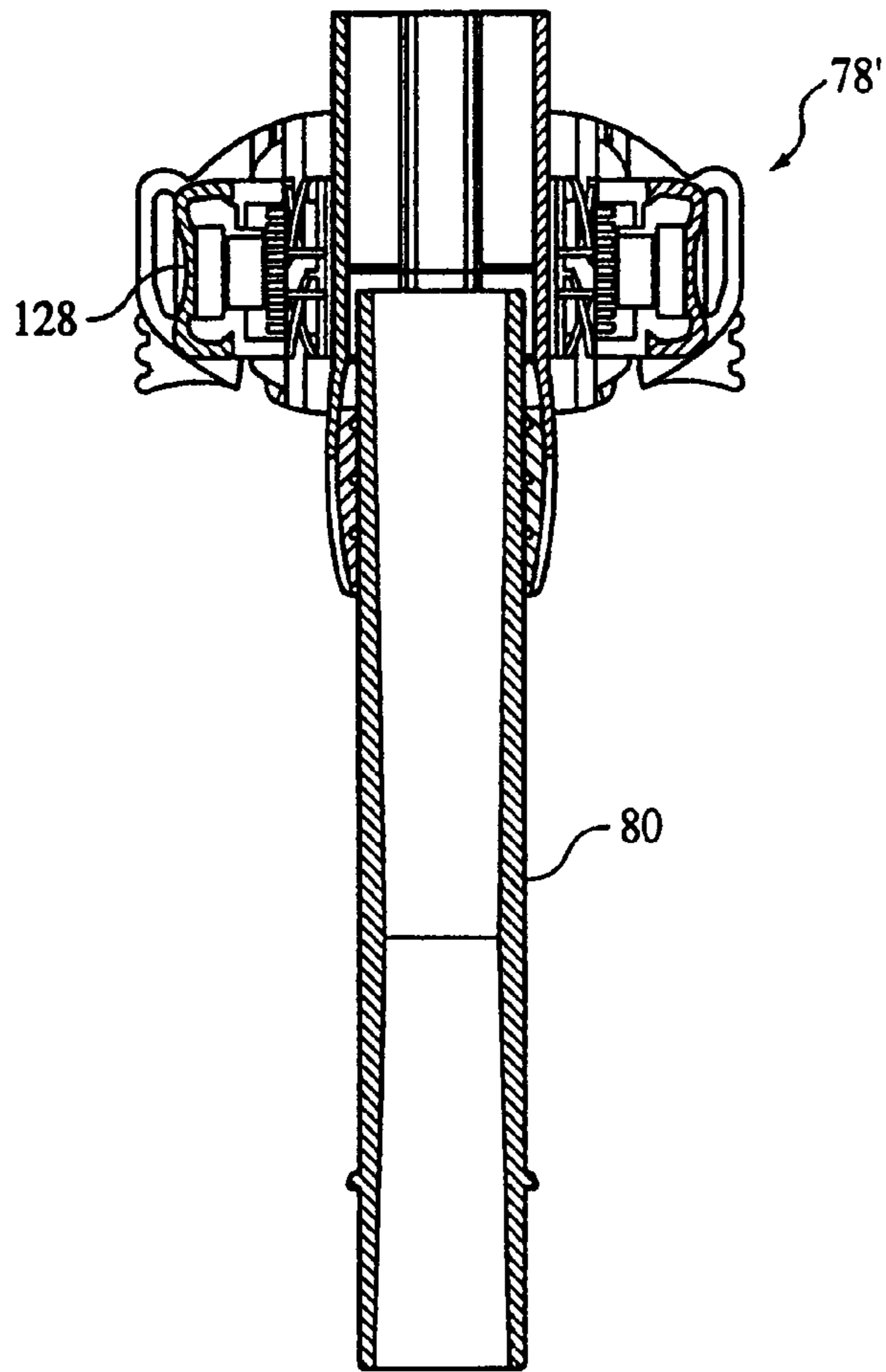


FIG. 21C

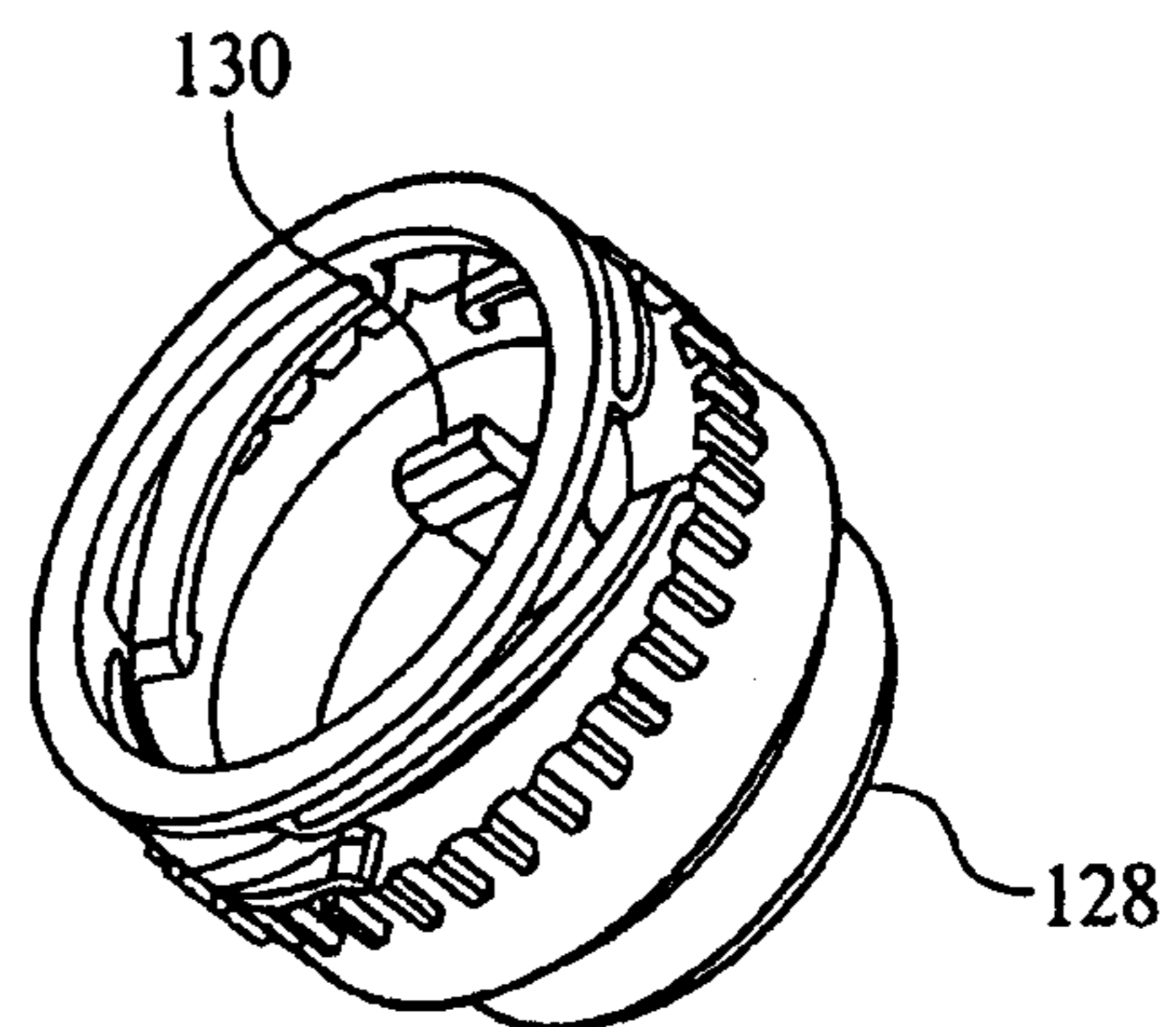


FIG. 21D

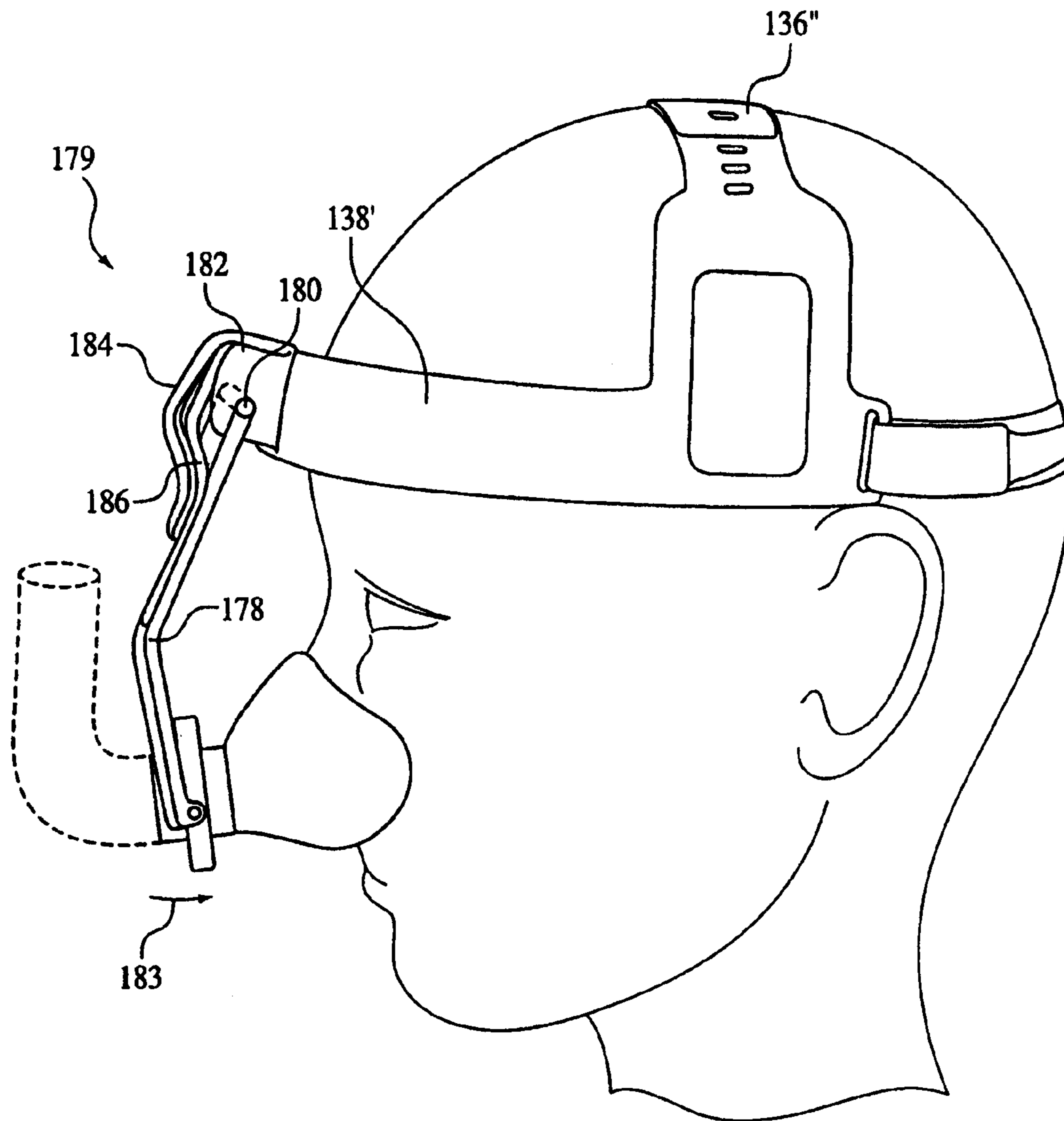


FIG. 22A

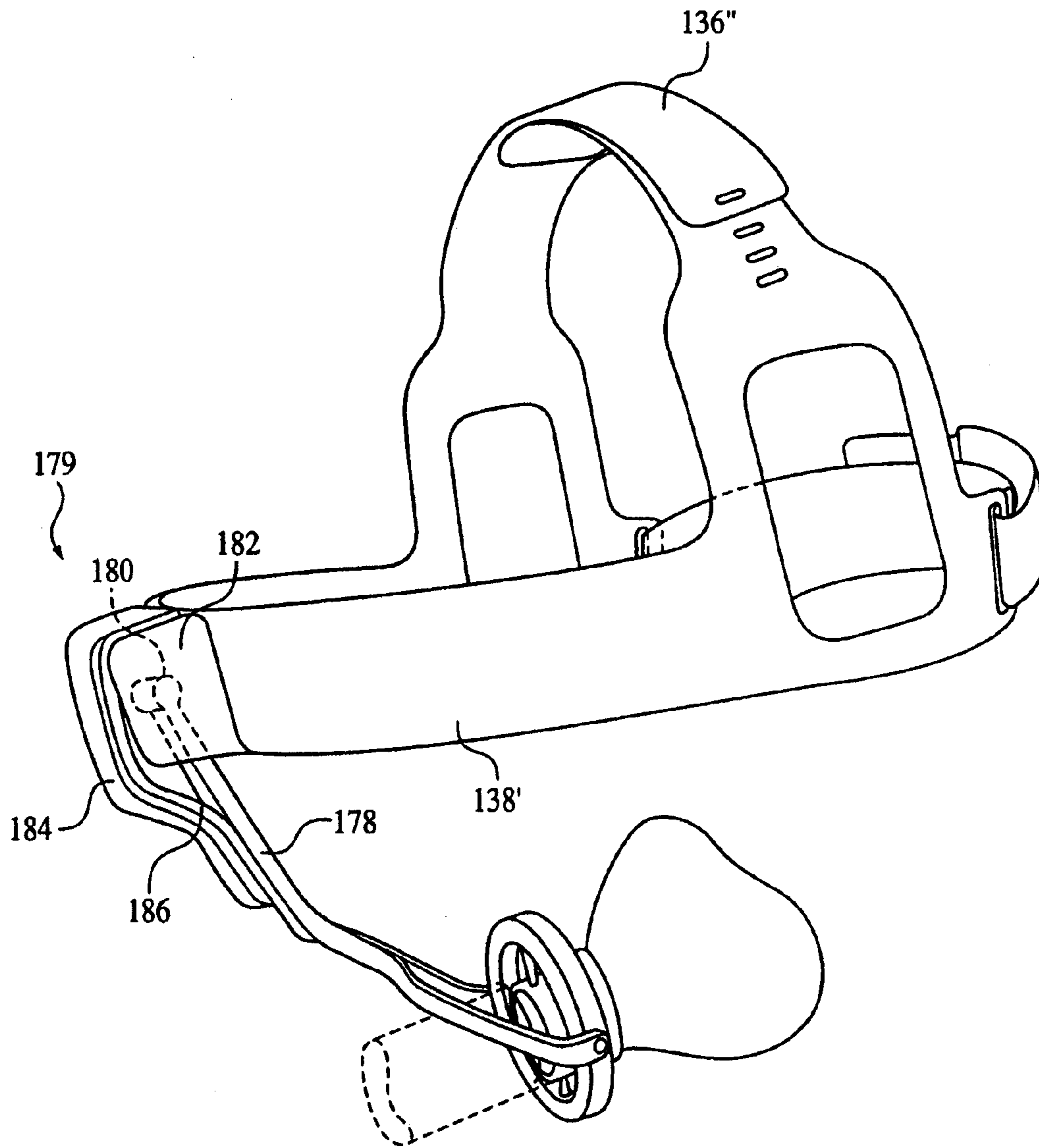


FIG. 22B

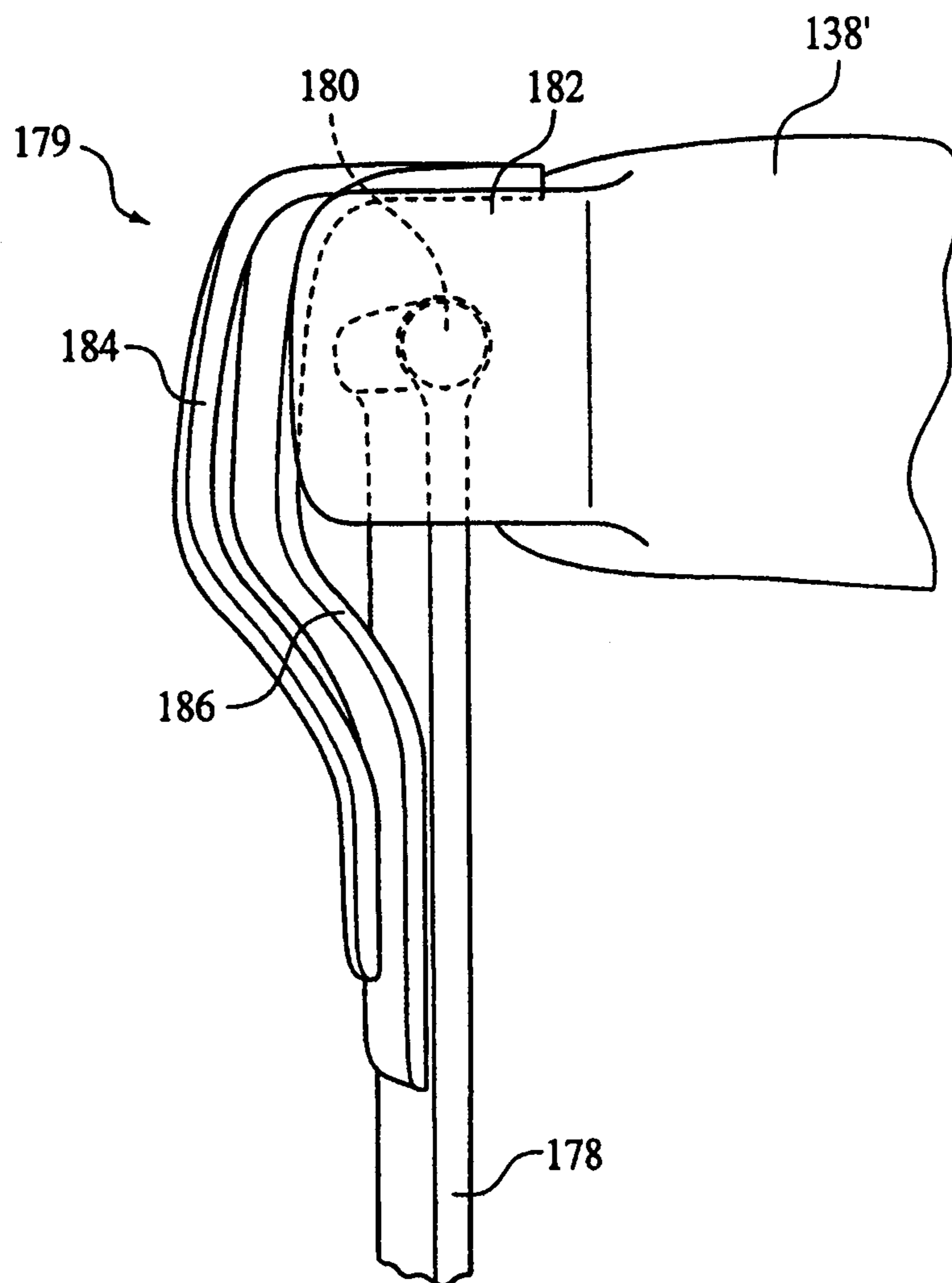


FIG. 22C

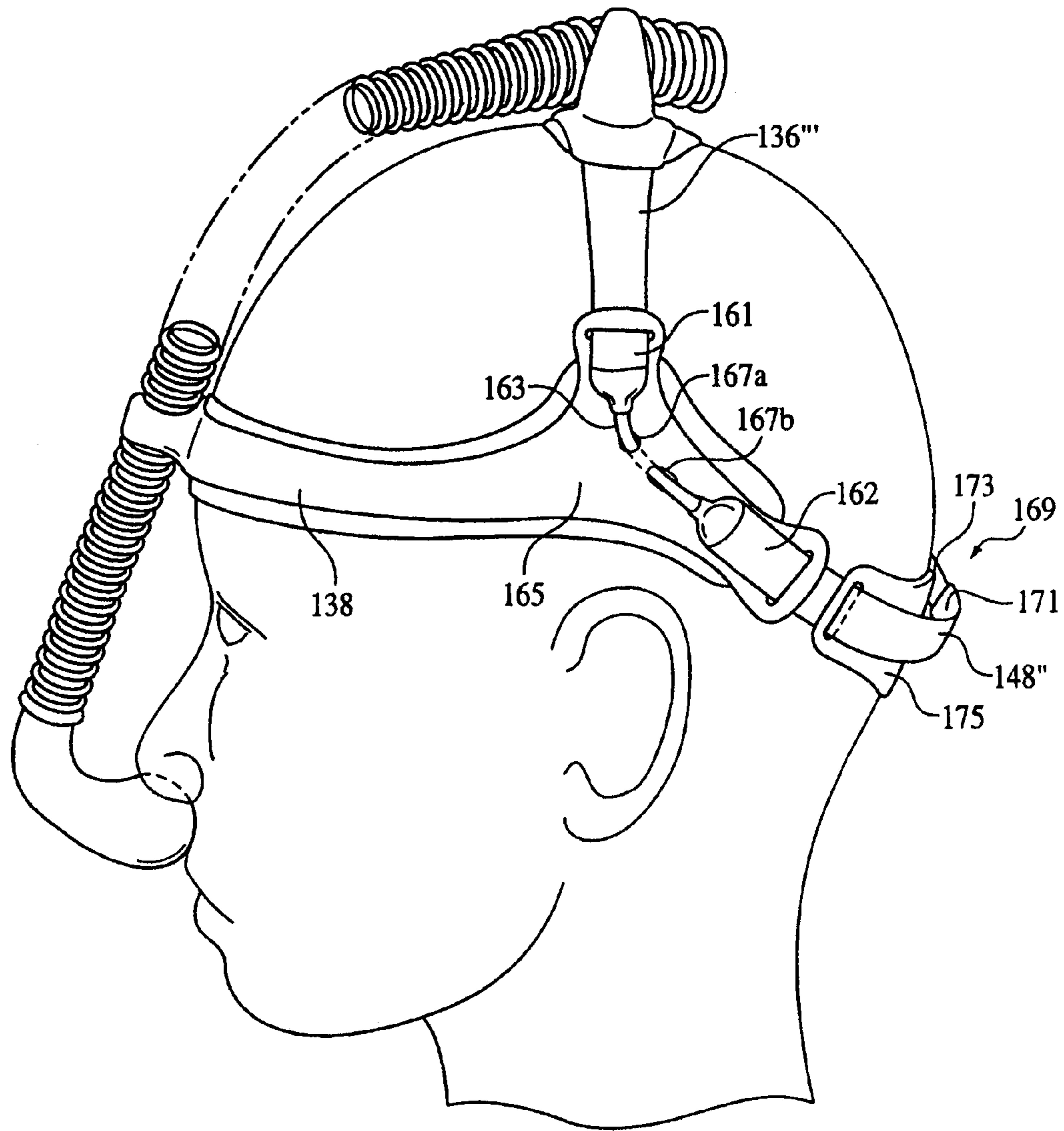


FIG. 23

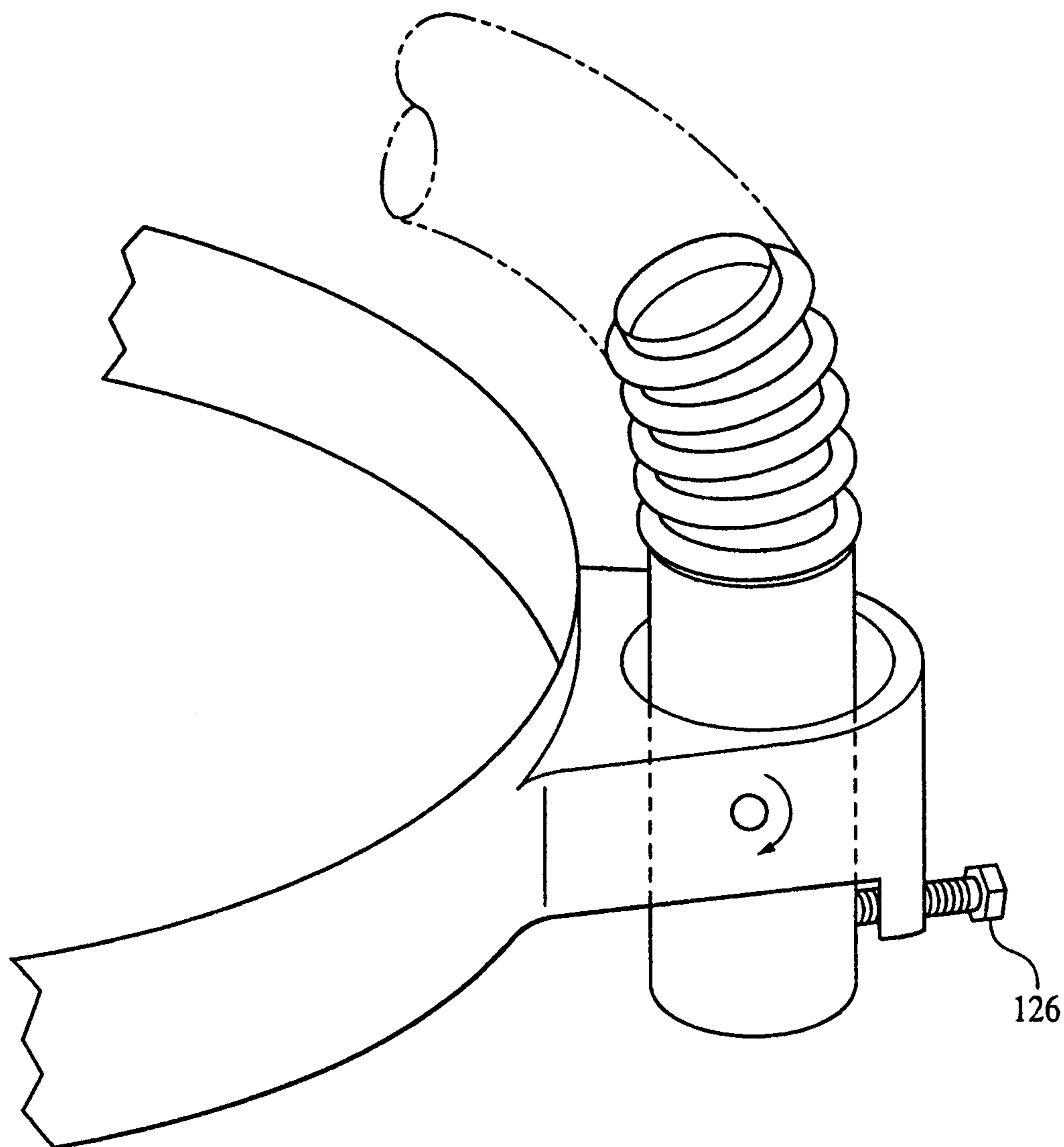


FIG. 24

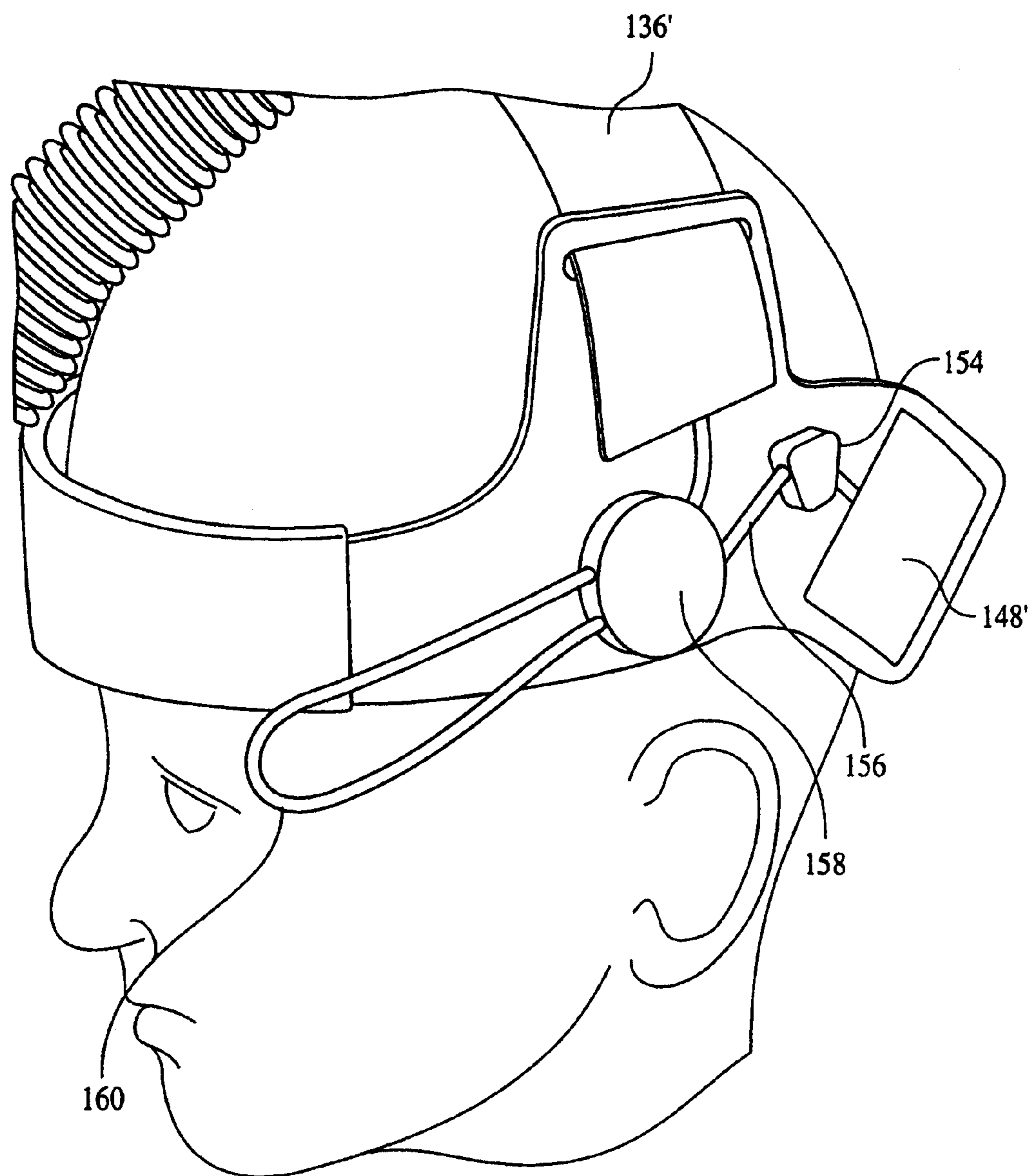


FIG. 25

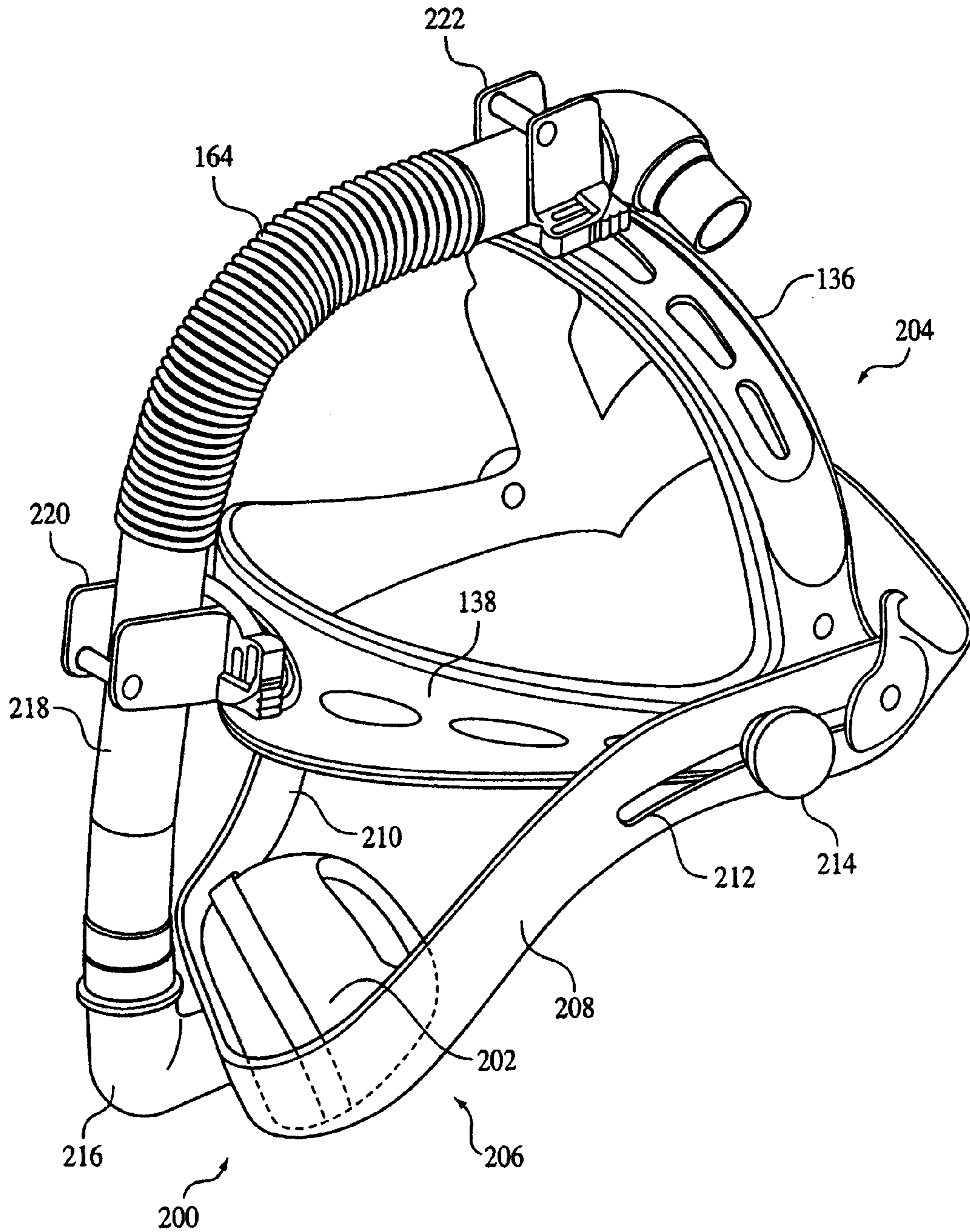


FIG. 26

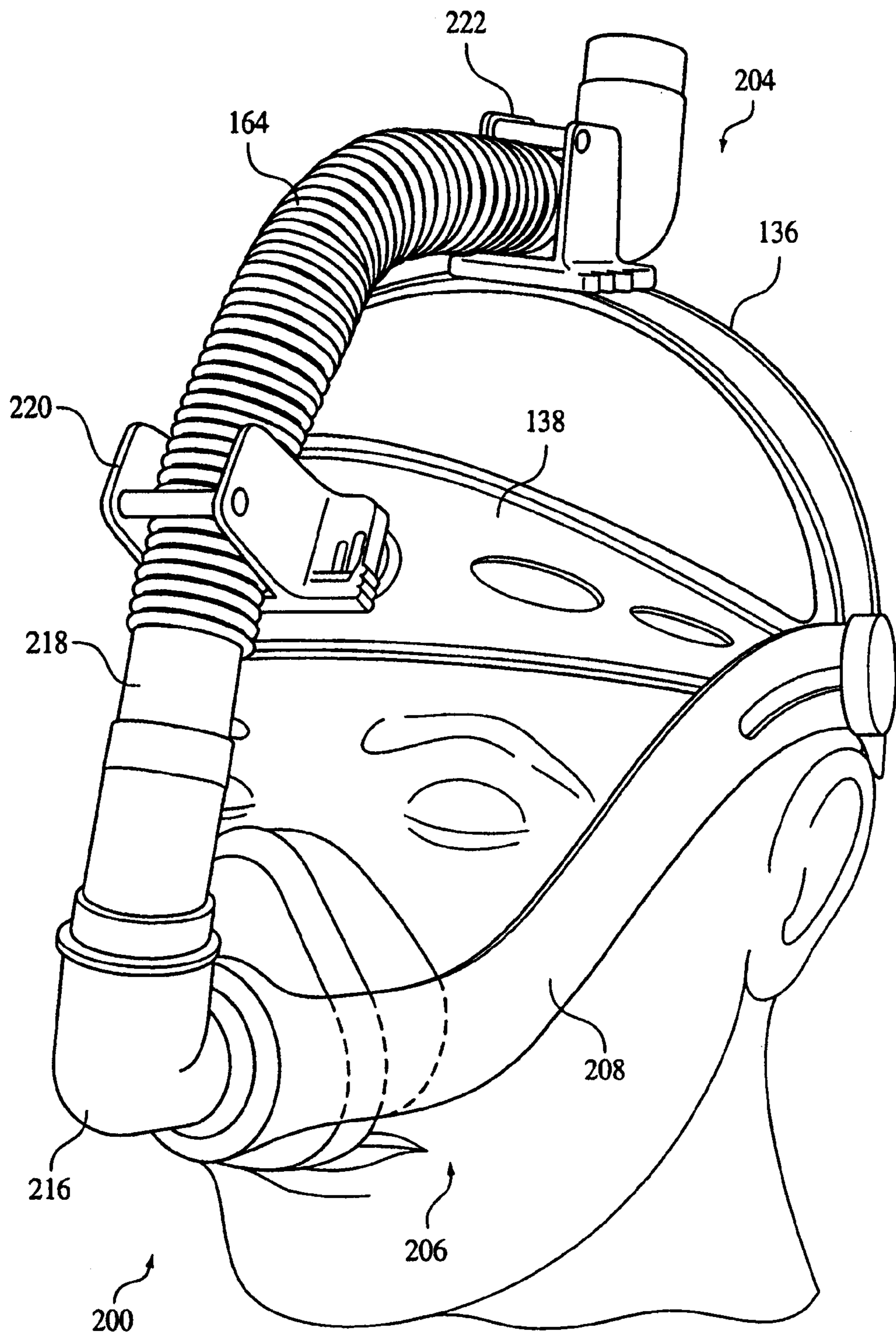


FIG. 27

**PATIENT INTERFACE ASSEMBLY AND
SYSTEM USING SAME**

CROSS-REFERENCE TO RELATED
APPLICATIONS

This application is a Divisional under 35 U.S.C. §120 of U.S. patent application Ser. No. 12/102,463, filed Apr. 14, 2008, which is a Continuation under 35 U.S.C. §120 of U.S. patent application Ser. No. 10/918,832, filed Aug. 13, 2004, now U.S. Pat. No. 7,357,136, which claims priority under 35 U.S.C. §119(e) from provisional U.S. patent application No. 60/496,059, filed Aug. 18, 2003, the contents of which are incorporated herein by reference.

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention pertains to a patient interface assembly, a system for supplying a flow of gas to a patient that incorporates such an assembly, and to a patient interface device and a headgear for use in such an assembly.

2. Description of the Related Art

There are numerous situations where it is necessary or desirable to deliver a flow of breathing gas, non-invasively, to the airway of a patient, i.e., without intubating the patient or surgically inserting a tracheostomy tube in their trachea. For example, it is known to ventilate a patient using a technique known as non-invasive ventilation. It is also known to deliver continuous positive airway pressure (CPAP) or variable airway pressure, which varies with the patient's respiratory cycle or a monitored condition of the patient, to treat a medical disorder, such as sleep apnea syndrome, in particular, obstructive sleep apnea (OSA), congestive heart failure, stroke, Cheynes-Stokes respiration, etc. Non-invasive ventilation and pressure support therapies involve the placement of a patient interface device, which is typically a nasal or nasal/oral mask, on the face of patient to interface the ventilator or pressure support device with the airway of the patient, so that a flow of breathing gas can be delivered from the pressure/flow generating device to the airway of the patient.

Because such patient interface devices are typically worn for an extended period of time, a variety of concerns must be taken into consideration. For example, in providing CPAP or other positive pressure therapy to treat OSA, the patient normally wears the patient interface device all night long while he or she sleeps. One concern in such a situation is that the patient interface device is as comfortable as possible, otherwise the patient may avoid wearing the interface device, defeating the purpose of the prescribed pressure support therapy.

Typically patient interface devices include a mask shell having a cushion attached to the shell that contacts the surface of the patient. The mask shell and cushion are held in place by a headgear that wraps around the head of the patient. The mask and headgear form the patient interface assembly. A typical headgear includes flexible, adjustable straps that extend from the mask to attach the mask to the patient. Other techniques for attaching a patient interface device use a vice-like device that anchors at the front and back of the patient's head to support the mask on the user. See, e.g., U.S. Pat. No. 6,516,802. While such conventional interface devices are generally well accepted, there remains a class of patients that do not find these devices to be sufficiently comfortable, too bulky, or

otherwise inadequate. Thus, alternative techniques for interfacing a pressure support system to the airway of a patient are desired.

SUMMARY OF THE INVENTION

Accordingly, the present invention provides a patient interface assembly that addresses the above-identified concerns and that overcomes shortcomings of conventional patient interface assemblies. The patient interface assembly of the present invention provides the patient with improved patient interface stability and overall comfort. The present invention further provides a system for delivering a flow of gas to a patient that addresses the above identified concerns and that does not suffer from the shortcomings of conventional techniques. This is achieved by providing a system for delivering a flow of gas to a patient that includes a gas flow generating device capable of producing a flow of gas and a conduit having a first end portion operatively coupled to the gas flow generating device and a second end portion. The conduit carries the flow of gas from the gas flow generating device. The system includes a patient interface assembly comprising a patient interface device operatively coupled to the second end portion of the conduit and a headgear.

The patient interface device, in one embodiment of the present invention, is a nasal interface device having a nasal cushion and a pair of laterally spaced nares elements for insertion into the nostrils of the patient. A formable support is preferably mounted to the nasal cushion for providing support for the nasal cushion while allowing for adjustments to provide increased fit and comfort of the nasal cushion. The nasal cushion is coupled to a coupling elbow or cradle having exhaust diffusion plates.

The headgear assembly of the present invention includes a substantially rigid, minimal contact harness assembly. The headgear of an exemplary embodiment includes an adjustment assembly that allows for a simultaneous adjustment of multiple straps.

A length adjustment assembly in one embodiment adjusts the distance between an adjustment assembly and the nasal interface device to accommodate patients having different facial sizes. The adjustment assembly is a position adjustment mechanism which provides a force adjustment by an integrated spring. The adjustment assembly allows a cantilevered support to support the patient interface device without a set of headgear straps located at the patient interface device.

In a further embodiment, the coupling member couples the patient interface device to the headgear and a spring, associated with the coupling member, biases the patient interface device against such a patient's face when the patient interface assembly being donned by such a patient. This ensures that the patient interface device is properly seated on the user.

In yet another embodiment, a rigid coupling member couples the patient interface device to the headgear. The rigid coupling member includes a first rigid arm connected between a first side of the patient interface device and a first side of the headgear and a second rigid arm connected between a second side of the patient interface device and a second side of the headgear. Preferably the length of the first and second arms is adjustable to properly fit the patient interface assembly on the patient.

These and other features and characteristics of the present invention, as well as the methods of operation and functions of the related elements of structure and the combination of parts and economies of manufacture, will become more apparent upon consideration of the following description and the appended claims with reference to the accompanying

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drawings, all of which form a part of this specification, wherein like reference numerals designate corresponding parts in the various figures. It is to be expressly understood, however, that the drawings are for the purpose of illustration and description only and are not intended as a definition of the limits of the invention. As used in the specification and in the claims, the singular form of “a”, “an”, and “the” include plural referents unless the context clearly dictates otherwise.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a side perspective view of a patient interface assembly according to the principles of the present invention;

FIG. 2 is a front view of the patient interface assembly of FIG. 1;

FIG. 3 is an exploded view of a nasal interface device and cradle in the patient interface assembly of FIG. 1;

FIG. 4 is a side view of the nasal interface device and cradle of FIG. 3;

FIG. 5 is an exploded view of the nasal interface device and formable support in the patient interface assembly of FIG. 1;

FIG. 6 is an exploded view of the cradle and an exhaust diffusion plate adapted to be disposed on the cradle in the patient interface assembly of FIG. 1;

FIG. 7 is a perspective view of the exhaust diffusion plate of FIG. 6;

FIG. 8 is a cross-sectional view of the exhaust diffusion plate of FIG. 7;

FIG. 9 is an exploded view of a length adjustment assembly and an angle adjustment assembly provided in the patient interface assembly of FIG. 1;

FIG. 10 is a side view of the length adjustment assembly and the angle adjustment assembly of FIG. 9;

FIG. 11 is a rear perspective view of the length adjustment assembly and the angle adjustment assembly of FIG. 9;

FIG. 12 is a cross-sectional view of the length adjustment assembly and the angle adjustment assembly of FIG. 9;

FIG. 13 is a side view of specific components of the angle adjustment assembly;

FIGS. 14-16 are perspective, front (partially in section), and top views, respectively, of the headgear and a mounting assembly in the patient interface assembly of FIG. 1;

FIGS. 17A and 17B are cross-sectional views and FIG. 17C is a top view of a nasal interface device according to a further embodiment of the present invention;

FIG. 18 is a perspective view of a nasal interface device and an alternate embodiment for the formable support;

FIG. 19A shows an exploded view of a nasal interface device and cradle according to another alternate embodiment, and FIG. 19B shows a perspective view of a nasal cushion and support according to the embodiment of FIG. 19A;

FIG. 20 is a cross-sectional side view of an alternate embodiment having a ball and socket connection;

FIG. 21A is a perspective view of an alternate embodiment for the length adjustment assembly and the angle adjustment assembly, FIG. 21B is a side view of the length adjustment assembly and the angle adjustment assembly of FIG. 21A, FIG. 21C is a cross-sectional side view of the length adjustment assembly and the angle adjustment assembly of FIG. 21A, FIG. 21D is a perspective view of the interior of the press and release buttons of the length adjustment assembly and the angle adjustment assembly of FIG. 21A;

FIGS. 22A and 22B are side and perspective views, respectively, of an alternate embodiment of the patient interface assembly of the present invention shown being worn by a patient, and FIG. 22C is a detailed view of the angle adjustment assembly of FIG. 22A;

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FIG. 23 is a side view of an alternate embodiment of the headgear assembly according to the principles of the present invention;

FIG. 24 shows another alternate embodiment of the angle adjustment assembly;

FIG. 25 shows another alternate embodiment of the headgear adjustment assembly for adjusting the fit of the headgear;

FIG. 26 is a perspective view of a still further embodiment of a patient interface assembly according to the principles of the present invention; and

FIG. 27 is a perspective view of the patient interface assembly of FIG. 26 shown being worn by a patient.

DETAILED DESCRIPTION OF THE EXEMPLARY EMBODIMENTS

FIGS. 1-16 illustrate an exemplary embodiment of a patient interface assembly 10 according to the principles of the present invention. The patient interface assembly 10 supports a patient interface device 12 on a patient's head. Patient interface device 12 communicates a flow of breathing gas between the patient's airway and a pressure generating device 14, such as a ventilator, CPAP device, or variable pressure device, e.g., a BiPAP® device manufactured and distributed by Respironics, Inc. of Pittsburgh, Pa., or an auto-titration pressure support system. A BiPAP® device is a bi-level device in which the pressure provided to the patient varies with the patient's respiratory cycle, so that a higher pressure is delivered during inspiration than during expiration. An auto-titration pressure support system is a system in which the pressure varies with the condition of the patient, such as whether the patient is snoring or experiencing an apnea or hypopnea. For present purposes, pressure generating device 14 is also referred to as a gas flow generating device, because flow results when a pressure gradient is generated.

Communicating a flow of breathing gas between the patient's airway and a pressure generating device 14 includes delivering a flow of breathing gas to the patient from the pressure generating device and exhausting a flow of gas from the patient to ambient atmosphere.

The system for delivering a breathing gas to a patient according to the present invention comprises a pressure or gas flow generating device 14 that produces a flow of gas, a conduit 16, which is also referred to as a patient circuit, having a first end portion 18 operatively coupled to the gas flow generating device and a second end portion 20. Conduit 16 carries the flow of gas from pressure generating device 14 during operation of the system to patient interface device 12 coupled to second end portion 20 of conduit 16. A headgear 22 according to the principles of the present invention, includes a mounting assembly 24 that couples patient interface device 12 to conduit 16, and an adjustable harness assembly 26.

In the illustrated embodiment the patient interface device 12 is a nasal interface device. However, the present invention also contemplates that other devices for communicating a flow of gas to an airway of a patient, such as a nasal mask, oral mask, or mouthpiece, or combination nasal/oral masks, are suitable for use as patient interface device 12.

Patient interface device 12 is generally a nasal interface having a nasal cushion 28 and a pair of laterally spaced nares elements 30 at its distal end for insertion into the nostrils of the patient. See FIGS. 3-4. The body of nasal cushion 28 includes a hollow chamber and extends from an oval shaped opening 32 to laterally spaced outlet legs 34. Each outlet leg 34 is provided with one of nares element 30. The body of

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nasal cushion **28** curves about an axis substantially perpendicular to a plane separating the two nares elements. Each nares element **30** has an opening **36** to communicate with the nasal passages of the patient. Each of nares elements **30** is substantially dome-shaped having an elliptical base proportional to anthropometrical data of a nostril opening. Nasal cushion **28** is preferably formed from a soft cushiony material, such as silicone, appropriately soft thermoplastic elastomers, closed cell foam, or thin materials.

The curved surface of nasal cushion **28** includes an inner curved surface **38** and an outer curved surface **40** substantially concentric to inner curved surface **38**. See FIG. 4. A formable support **42** is preferably mounted to outer curved surface **40**. Formable support **42** provides support to nasal cushion **28** while allowing for adjustments to provide increased fit and comfort of the nasal cushion. In the illustrated embodiment, formable support **42** is substantially T-shaped having a stem portion **44** and a cross portion **46**. See FIG. 5. Cross portion **46** extends from one end of stem portion **44** at a cross portion midpoint **48**. Ends **50** of cross portion **46** curve from midpoint **48**.

In the illustrated embodiment, outer curved surface **40** of nasal cushion **28** includes mounting tabs **52** to mount to ends **50** of cross portion **46** of support **42**. Ends **50** of the cross portion **46** have through-holes **54** to mount to the corresponding mounting tabs **52**. See FIG. 5.

Formable support **42** is preferably formed from a formable metal, such as aluminum. Support **42** can be conformed by pressing on the support with the patient's or caregiver's fingers. By manipulating the support, the angle of the nasal cushion with respect to the facial-frontal plane, and/or the angle of nare contact of the nares elements can be changed.

Alternatively, formable support **42** could be formed from Nitinol (Nickel Titanium Naval Ordinance Laboratory), which is known as shape memory metal, or a plastic with a low softening point temperature, such as EVA (Ethylene Vinyl Acetate) could be used. EVA is commonly used in boil and bite mouthpieces that athletes use. The EVA support in this case could be warmed in hot water and then formed.

While the illustrated formable support **42** is T-shaped, alternatively, the support could be Y-shaped. T or Y-shaped supports **42** can be hollow or solid. While the illustrated embodiments show externally mounted supports, the supports could also be molded within the nasal cushion itself. Alternatively, formable support **42** could be bonded to the cushion in discreet locations. An alternate shaped formable support **56** is illustrated in FIG. 19A. In the embodiment of FIG. 18, support **56** is formed from a formable wire generally following the outline of outer curved surface **40** of nasal cushion **28**. By having formable support **56** connected to nasal cushion **28** at discreet locations, there is some relative movement between nasal cushion **28** and support **56** during adjustment of the support.

In FIGS. 19A and 19B, which illustrate further exemplary embodiments for the formable support, the support is mounted to outer curved surface **40** of nasal cushion **28** using three pockets **59** provided on outer curved surface **40**. Each pocket receives an end portion of the formable support. The configurations for attaching the formable support to the nasal cushion shown in FIGS. 3, 4, 18, and 19A-19B provide an advantage in that the formable support can be readily attached and detached from the nasal cushion. This allows formable supports of different stiffness to be used in the same nasal cushion and allows for easy replacement of the nasal cushion or the formable support.

The present invention contemplates varying a property of the walls forming nasal cushion **28**, outlet legs **34**, and nares

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elements **30**, such as the thickness and/or elasticity, to provide performance improvements in the patient interface, such as increased comfort, better mask/patient seal, and/or greater customization capability. For example, FIGS. 17A-17C illustrates a nasal cushion wall **55** that is relatively thick. A base portion **57** of a nares element wall **61** is also relatively thick, but tapers as the distance from base portion **57** increases. Between the relatively thick walled based portion **57** of nares element wall **61** and nasal cushion wall **55** is a relatively thin wall portion **63**. Providing thin wall portion **63** between these two thick walls allows nares element **30** to articulate relative to nasal cushion **28** so that the nares element better fits the nostrils of the user. In addition, the formability of the nasal cushion is increased by providing a relatively deep spacing between outlet legs **34**. It is to be understood that a similar function, whereby the nares elements are moveable relative the nasal cushion, can be achieved without varying the thickness of the walls. For example, a material having a relatively high degree of elasticity (stretchable) can be provided at location **63**, while walls **55** and **61** are formed from a material of lower elasticity. Of course, a combination of varying wall thickness and elasticity are also contemplated by the present invention.

In the illustrated embodiments, with the possible exception of that shown in FIGS. 19A and 19B, stem portion **44** of T-shaped formable support **42** is receivable in a corresponding notched portion **68** provided in oval shaped opening **60** of cradle **58**. Alternatively, formable support **42** can be mounted to nasal cushion **28** by corresponding pockets on outer curved surface **40** of nasal cushion **28**, as shown in FIGS. 19A and 19B.

In the present invention, oval shaped opening **32** of nasal cushion **28** is coupled to a coupling elbow or cradle **58**. Cradle **58** is substantially curved having an oval shaped opening **60** that connects to oval shaped opening **32** of nasal cushion **28**. In the illustrated exemplary embodiment, cradle **58** has a double wall construction **62** and forming a hollow chamber **64**. An opposite end **66** of the cradle is substantially circular. See FIGS. 3-4. It is to be understood, however, that the present invention contemplates joining nasal cushion **28** and cradle **58** using other configurations for the cooperating parts. For example, a groove (double wall) can be provided in the end of nasal cushion **28** so that the end of cradle **58** fits into the groove formed in the cushion.

In the illustrated embodiment, tabs **67** are provided on opposing sides of nasal cushion **28** at end **66**. Corresponding tab receiving slots **69** are provided on cradle **58** for receiving tabs when the nasal cushion is properly coupled to the cradle. Tabs **67** and slots **69** assist in aligning the cushion with the receiving end of the cradle. To help retain cradle **58** and cushion **28** in an engaged relation, tabs **67** and slots **69** are configured and arranged so that the tab cannot be easily pulled apart. For example, in the illustrated embodiment, slot **69** has an "arrow" shape and tab **67** is a similar shape. This "arrow" shape allows the tab to be readily inserted into the slot due to the wedge-shaped tip of the arrow, but prevents disengagement due to the flat back end of the tab abutting the flat back ends of the arrow-shaped slot. Of course, other configurations for tab **67** and slot **69** are provided for accomplishing these functions. In addition, the tab can be provided on the cradle and the slot provided in the cushion.

As shown in FIGS. 4 and 6-8, an outer curved surface **70** of cradle **58** includes an exhaust diffusion plate **72** having diffusion holes **74** for exhausting exhaled gas from the pressurized system to the atmosphere. Preferably, exhaust diffusion plate **72** includes diffusion holes **74** having a tapered diameter and arranged in a fan pattern. In the illustrated embodiment,

exhaust diffusion plates 72 provide a substantially 180 degree radial diffusion. It is to be understood that the present invention contemplates forming the diffusion plate at other locations on the cradle and forming the holes in the diffusion plate in any desired configuration to achieve an almost infinite number of different diffusion patterns. For example, multiple diffusion plates can be provided so that diffusion plates are provided at various locations on the cradle. In addition, the holes, which are otherwise provided in the diffusion plate, can be formed directly in the wall of the cradle. In which case, the diffusion plate(s) can be eliminated. Of course, a combination of exhaust ports defined directly in the wall of the patient interface device and a diffusion plate(s) can also be used. Diffusion plate 74 is preferably formed from a rigid material. However, the present invention also contemplates that the diffusion plate can be formed from a material that is deformable.

End 66 of cradle 58 is connected to a length adjustment assembly 76, which adjusts the distance between an angle adjustment assembly 78 and nasal interface device 12, to accommodate patients having different facial sizes. As shown in FIGS. 1-2 and 9-13, length adjustment assembly 76 includes a tubular section 80 and an adjustment nut 82. Tubular section 80 is received within adjustment nut 82. A lower end 84 of tubular section 80 is connected to circular end 66 of cradle 58 using any conventional technique, such as a friction fitting. Threading 86 is provided on the exterior of tubular section 80 and on an interior of adjustment nut 82. Length adjustment is accomplished by rotating adjustment nut 82 so that the threading on adjustment nut 82 engage the threading on tubular section 80. Rotating adjustment nut 82 causes tubular section 80 to move up or down inside a pivot tube 88 coupled to adjustment nut 82. Pivot tube 88 is part of angle adjustment assembly 78, which is described in greater detail below.

Angle adjustment assembly 78, which is best shown in FIGS. 9-13, is a position adjustment mechanism with prefixed angular locating positions to control the position or angle of the rigid gas flow conduit relative to the patient's face over a relatively large range of angles, e.g., a 45° range. In addition to this relatively large adjustment capability, angle adjustment assembly provides a force adjustment by means of an integrated spring on a secondary pivoting member over in a narrower range of angles, e.g., 5° range. The angle adjustment assembly allows a cantilevered support to support the patient interface device without a set of headgear straps located at the patient interface device.

Angle adjustment assembly 78 includes an adjustment mechanism that itself includes a mounting bracket 90, an angular pivot housing 92, and a pivot tube 88. Mounting bracket 90 is attached to harness assembly 26 of headgear 22 and comprises a pair of substantially parallel mounting bracket arms 94 extending from a harness assembly attaching portion 96. Each mounting bracket arm 94 is substantially L-shaped and extends outward from harness assembly attaching portion 96 of mounting bracket 90 to a bend portion 98 before extending upwardly to a distal portion 100. Each distal portion 100 includes a plurality of spaced locking/adjustment key holes 102. In the illustrated embodiment, nine key holes 102 are provided on each distal portion 100 corresponding to nine preset positions, which are about 5 degrees apart covering a total angular range of 45 degrees.

Bend portion 98 of each mounting bracket arm 94 includes a pivot hole 104. A pivot axis 106 extends between pivot holes 104 in mounting bracket arms 94. Both angular pivot housing 92 and pivot tube 88 pivot relative to mounting bracket 90 independently about axis 106. Angular pivot housing 92 is

mounted between the mounting bracket arms 94 and includes a substantially circular bracket 108 having an interior annular opening 110 and a pair of substantially parallel extension arms 112 extending from opposite sides of circular bracket 108. Circular bracket 108 has a pair of slots 114 having pivot holes 116 corresponding to mounting bracket pivot holes 104. A distal end 118 of each extension arm 112 includes a rigid oval portion (FIG. 13) or a flat rectangular portion, as shown in FIGS. 11-12, functioning as a thumb rest.

On the exterior portion of each extension arm 112, intermediate circular bracket 108 and distal end 118, there is provided an extension key 120 adapted for locking/adjustment engagement with the plurality of locking/adjustment key holes 102 of corresponding mounting bracket arm 94. The angular position of angular pivot housing 92 relative to mounting bracket 90 is locked by two extension keys 120 on extension arms 112 of angular pivot housing 92. In the illustrated embodiment, the locking is dual directional, but could also be a one-directional ratchet type. The angular position of angular pivot housing 92 relative to mounting bracket 90, and thus, the angular position of patient interface device 12 relative to the forehead of the patient, can be released and adjusted by squeezing and moving the two thumb rests at distal ends 118 of extension arms 112 to move extension keys 120 from one angular position to the next and then releasing the thumb rests so locking/adjustment keys 120 are engaged within the desired locking/adjustment key holes 102. This angular positioning of the angular pivot housing is illustrated by arrow 107 in FIG. 13.

Pivot tube 88 is a rigid tubular member mounted within interior annular opening 110 of circular bracket 108. A pair of pivot projections 122 extend from opposite sides of the exterior of pivot member 88. When assembled, each pivot projection 122 extends through a corresponding circular bracket pivot hole 116 and then through a corresponding mounting bracket arm pivot hole 104. Pivot tube 88 pivots relative to mounting bracket 90, but its motion is restricted by angular pivot housing 92. Pivot tube 88 provides a second range of movement of about 5 degrees.

As shown in FIGS. 11 and 13, pivot tube 88 is biased by an integrated lever spring 124 provided on circular bracket 108 intermediate extension arms 112. The bias provided by the lever spring is illustrated by arrow 115 in FIG. 13. Pivot tube 88 is pushed inwardly (deflected toward the user when in use) to the most inner position with respect to the angular pivot housing 92 by spring 124. Pivoting of pivot tube 88 against the bias force is limited by contact with the integrated lever spring 124.

In an alternate embodiment shown in FIG. 24, a thumb-screw 126 is mounted on the front of the pivot tube below the centerline of the pivot. By rotating the screw, the tube is pushed toward the user when donned by the user. Alternatively, the screw could be mounted above the pivot so that rotating the screw causes the tube above the pivot to be pushed out, which, in turn, push the tube below the pivot toward the user. Additionally, a torsion spring could be mounted on the pivots to provide a spring force biasing the position of the patient interface toward the user. Of course, other spring type arrangements can be provided on angle adjustment assembly 78 to bias the patient interface device at end 84 of tube 80 toward the user.

An alternate embodiment of angle adjustment assembly 78' is shown in FIGS. 21A-21D. In this embodiment, angle adjustment assembly 78' includes a pair of press-and-release buttons 128 with a built-in spring 130 action. Press-and-release buttons 128 are operated by pressing the buttons to

disengage a locking mechanism, thereby allowing tube **80** to rotate relative to mounting bracket **90'** to the desired position.

In a further alternate embodiment, the coupling between the patient interface device and the coupling elbow or cradle is adjustable. An example of this is shown in FIG. **20**. More specially, FIG. **20** illustrates a coupling between cradle **58'** and a nasal mask **131**. This illustrated coupling is a ball **132** and socket **134** type joint, where the ball is allowed to rotate within the socket. More specifically, cradle **58'** includes a ball end **132**, which is receivable in a socket portion **134** of the patient interface device, thereby allowing the tubing portion to be angled or rotated with respect to the patient interface device. Friction between the ball and socket maintain the position between these two elements once they are moved to the desired position. Although a ball-and-socket type of configuration is shown, it is to be understood that other adjustable type joints could be used for coupling the patient interface device to the elbow/cradle. In addition, the ball-and-socket arrangement can be reversed, with the ball being provided on the patient interface and the socket on the elbow/cradle.

As shown in FIGS. **1**, **2**, and **14-16**, harness assembly **26** of headgear **22** is adapted to be worn on the head of a patient and includes a cross strap **136** extending over the top of the patient's head and a forehead strap **138** extending over the forehead and temples of the patient. Forehead strap **138** and cross strap **136** are formed from a semi-rigid plastic and preferably have a cushioning element on the patient contacting side. Each end **140** of forehead strap **138** includes an angled connecting port **142** for adjustable connection to cross strap **136**. In the illustrated embodiment, each angled connecting portion **142** includes five adjusting holes **144**, while each end of the cross strap **136** includes two corresponding projections **146** enabling the corresponding connecting portion **142** of forehead strap **138** and the ends of cross strap **136** to be selectively interconnected to adjustable lengths depending on the head parameters of the patient to provide a secure fit. It can be appreciated that each side of cross strap **136** can be adjusted independently of the other side. In addition, the hole and projections can be reversed, and more or less holes and projections can be provided.

Harness assembly attaching portion **96** of mounting bracket **90** is attached to a center portion of forehead strap **138**. In an exemplary embodiment of the present invention, harness assembly attaching portion **96** is releasably attached to a mounting bracket **166** provided on forehead strap **138**. See FIGS. **14-16**.

A rear strap **148** is provided having a rigid connecting element **150** on each end. Each connecting element **150** is receivable in a key slot opening **152** provided on angled connecting portion **142** below the cross strap adjusting holes **144**. Rear strap **146** loops through connecting elements **150** and is adjusted by hook and loop fasteners or other appropriate means. Thus, each end of rear strap **146** is selectively attachable to the semi-rigid headgear portions and the length of the rear strap is adjustable on either end. Those skilled in the art will appreciate that the connecting element **150** and slot **152** arrangement can be reversed, with the slot or other female receiving portion provided on the rear strap and the connecting element and the other cooperating male portion provided on angled connecting portion **142**.

Alternatively, as shown in FIG. **25**, adjustment of harness assembly **26** is accomplished by means of an adjustment assembly **154**, which simultaneously adjusts both cross strap **136'** and rear strap **148'**. Specifically, cross strap **136'** and rear strap **148'** are linked together on one side of harness assembly **26** via a connecting element **156**, such as a cord. Connecting element **156** is attached to adjacent ends of cross **136'** and rear

148' straps. Connecting element **156** is threaded through a locking element **158** forming a loop **160**. The effective length of cross strap **136'** and rear strap **148'** is adjusted by adjusting the size of the connecting element loop **160** through locking element **158**. Thus, the positions of cross strap **136'** and rear strap **148'** about the patient's head are simultaneously adjusted by the single adjustment of the connecting element **156**.

It should be noted that the present invention contemplates eliminating loop **160** in favor of allowing cross strap **136'** and rear strap **148'** to be adjusted independently. That is, separate connecting elements can be provided for cross strap **136'** and rear strap **148'** so that each can be adjusted by means of locking element **158**.

FIG. **23** illustrates a further embodiment for controlling the adjustment of the harness assembly. In this embodiment, end portions **161** and **162** of cross strap **136''** and rear strap **148''**, respectively, are connected to one another via a connecting member **163**. In the illustrated embodiment, connecting member **163** is a cord that is connected to portion **165** of the headgear assembly. More specifically, connecting member **163** runs through holes **167a**, **167b** provided in portion **165**. Cross strap **136''**, rear strap **148''**, or both, include a strap tightening system **169**, which in the illustrated embodiment is shown as being provided on rear strap **148''**.

Strap tightening system **169** is any conventional system that is used to increase or decrease the length of the strap, such as a hook and loop configuration. In the illustrated exemplary embodiment, hooks **171** are provided on strap **148''** and corresponding loops **173** are provided on a pad **175**. Of course, this configuration can be reversed. Tightening of strap **148''** is accomplished by pulling more of the strap across the pad and fastening the strap back onto the pad.

Because of the connection between cross strap **136''** and rear strap **148''** provided by connecting member **163**, tightening or shortening the length of one of these straps has the effect of simultaneously tightening or shortening the length of the other. Thus, this embodiment for the headgear provides a single means (strap tightening system **169**) for adjusting the one strap that automatically adjusts another strap in the headgear.

Referring again to FIGS. **1**, **2**, and **14-16**, the upper end of tubular section **80** of length adjustment assembly **76** is connected to an air hose **164**. Cross strap **136** further includes mounting bracket **166** for mounting a crown swivel **168** for attaching air hose **164** to conduit **16**. Crown swivel **168** includes a lower tubular member **170** and an upper tubular member **172** each connected to a swivel joint **174**, so that the lower tubular member **170** and the upper tubular member **172** can freely swivel. The lower tubular member **170** includes a clip portion **176** for selectively and releasably connecting mounting bracket **166** to cross strap **136**. In an exemplary embodiment of the present invention, clip portion **176** selectively connects mounting bracket to strap **136** in the same manner as harness assembly attaching portion **96** attaches to forehead strap **138** discussed below.

Referring now to FIGS. **11**, **12**, and **14-16**, the manner in which harness assembly attaching portion **96** attaches to forehead strap **138** and lower tubular member **170** attaches to cross strap **136** will now be discussed. It should be noted that the manner in which assembly attaching portion **96** is attached to forehead strap **138** and the manner in which an attaching portion **96'** disposed on lower tubular member **170** is attached to cross strap **136** are substantially similar. Thus, reference is made only to one of these attachment configurations, namely the attachment of attachment portion **96'** on

lower tubular member **170** to cross strap **136**, and only this attachment configuration is shown in FIGS. **14-16**.

Cross strap **136** and forehead strap **138** each includes a mounting bracket **166** on which the corresponding attaching portion **97, 97'** attaches. Please note that only the mounting bracket on the cross strap is shown. Each attaching portion **96, 96'** includes clip portions **97, 97'** on each side of attaching portion **96, 96'**. Squeezing clip portions **97, 97'** toward one another causes them to deflect from a biased position, where an engaging portion **99, 99'** engages a portion **101** of mounting bracket **166**, to a deflected position, where engaging portion **99, 99'** disengages from portion **101**, thereby allowing the attaching portion to slide off of the mounting bracket. See FIGS. **11** and **12**.

Preferably, mounting bracket **166** and attaching portion **96, 96'** are configured such that they can only be assembled in one orientation to ensure that the patient interface assembly is assembled correctly. The ability to attach and detach mounting assembly **28** and angle adjustment assembly **78** from the corresponding portion of the headgear assembly allows the components of the patient interface assembly to be disassembled for easy cleaning and allows for easy part replacement.

A still further alternate embodiment is shown in FIGS. **22A-22C**. In this embodiment, there is no length adjustment assembly **76**, but there is a biasing assembly, generally indicated at **179**, for the patient interface device, which in this embodiment, is a nasal mask. The nasal mask is attached to one end of a lever bar **178**. The opposite end of the lever bar is connected to a pivot **180** on a mounting bracket **182** located at the central portion of the forehead strap. An integrated spring **184** is provided on the mounting bracket to bias the patient interface device toward the user when the patient interface system is donned by the user, as indicated by arrow **183**. Spring **184** may be fixed or adjustable to allow an increasing or decreasing sealing force. This adjustment would typically be made based on the patient's individual prescription pressure. In the illustrated embodiment, a second spring **186** is provided on mounting bracket **182** to provide an additional bias force on lever bar **178**. Of course, this second spring is optional.

It is also to be understood that the present invention contemplates that other spring biasing techniques, in place or in addition to those shown in the figures, can be used to urge the patient interface device toward the patient. For example, a spring can be provided on the patient side of level bar **178** and attached to mounting bracket **182** or the forehead strap.

FIGS. **26** and **27** illustrate another embodiment of a patient interface assembly **200** according to the principles of the present invention, in which FIG. **27** shows the patient interface assembly as worn by a patient. Patient interface assembly **200** includes a patient interface device **202** and a headgear **204** adapted to be worn by the patient. In the illustrated embodiment, patient interface device **202** is a nasal mask adapted to cover the area of the face surrounding the nares. It is to be understood that the patient interface device can correspond to any conventional interface device or the interface device **12** discussed above. Headgear **204** corresponds to headgear **22** discussed above and can include all of the features of that headgear.

One difference between the patient interface assembly of FIGS. **26** and **27** and that of the previous embodiment is in the manner in which the patient interface device is biased or held against the surface of the patient. In the embodiment of FIGS. **26** and **27** a rigid coupling member, generally indicated at **206**, couples patient interface device **202** to headgear **204**. The rigid coupling member includes a first arm **208** con-

nected between a first side of the patient interface device and a first side of the headgear, and a second arm **210** connected between a second side of the patient interface device and a second side of the headgear, wherein the first and the second arm are rigid. The first and second arms are preferably formed from a light-weight material, such as plastic. In addition, the first arm and the second arm are also preferably sized and shaped that they generally match the contour of a human face that underlies each arm when the patient interface assembly is donned by the patient.

In a preferred exemplary embodiment of the present invention, the first arm and the second arm are adjustably coupled to the headgear such that the length of the first and second arms can be controlled to fit the needs of each patient. In the illustrated embodiment, this adjustable connection is achieved by providing a slot **212** in the end of first arm **208** and at the end of the second arm. Of course, only the first arm is shown in FIGS. **26** and **27**. A friction lock **214** is disposed in the slot. The friction lock includes a post that is disposed in the slot and a lock nut that is threaded onto the post. Loosening the nut allows the post to move along the slot, and tightening the nut causes the nut to hold the friction lock in place. It is to be understood that the present invention contemplates using any conventional technique for controlling the positions of the first and second arms relative to the headgear.

The first and second arms can be connected to the patient interface device in a fixed relationship, i.e., such that the arms do not move relative to the mask shell, or in a non-fixed relationship. In an exemplary embodiment, the non-fixed relationship includes coupling the arms to an elbow connector **216** such that the arms swivel or rotate about this connector. For example, the present invention contemplates that the first and second arms are defined from an integral piece of material with a hole defined therein. The elbow coupling is disposed in the hole such that the arms can rotate around the elbow coupling.

As in the previous embodiment, a connector tube **218** is connected to elbow coupling **216** and an air hose **164** is coupled to tube **218**. A connecting element **220** is provided to couple air hose **164** and/or coupling tube **218** to a forehead strap **138**. If desired, another coupling element **222** can be provided at cross strap **136** to connect the patient circuit to the headgear. Connecting elements **220** and **222** can be any conventional device that secures the tube to the headgear, such as a simple strap, or they can correspond to the coupling systems discussed above.

Although the invention has been described in detail for the purpose of illustration based on what is currently considered to be the most practical and preferred embodiments, it is to be understood that such detail is solely for that purpose and that the invention is not limited to the disclosed embodiments, but, on the contrary, is intended to cover modifications and equivalent arrangements that are within the spirit and scope of the appended claims.

What is claimed is:

1. A patient interface device comprising:

- a nasal cushion formed from a first material, the nasal cushion having a body and a first nares element and a second nares element positioned at an end of the body, the first nares element being laterally spaced from the second nares element, the body curving about an axis that is perpendicular to a plane separating the first nares element and the second nares element, the body having a curved external surface; and
- a formable support formed from a second material different than the first material, wherein the formable support is attached to the curved external surface of the body and

includes a portion that extends over the curved external surface in a direction along and within the plane separating the first nares element and the second nares element, and wherein the formable support is adapted to be molded from a first pattern to a second pattern and to retain the second pattern after being so molded so as to enable a user to control a shape of the nasal cushion by altering the curve of the body about the axis, wherein the formable support is T-shaped or Y-shaped, wherein the portion of the formable support that extends over the curved external surface is a stem portion having a first end and a second end, wherein the formable support includes a cross portion provided at the second end, wherein the body includes a first pocket, a second pocket and a third pocket, wherein the first end of the stem portion is received in the first pocket, and wherein a first end of the cross portion is received in the second pocket and a second end of the cross portion is received in the third pocket.

2. The patient interface assembly of claim 1, wherein the formable support is formed from shape memory metal.

3. The patient interface assembly of claim 1, wherein the body has a second curved external surface opposite and concentric to the curved external surface.

4. The patient interface assembly of claim 1, wherein the cross portion has a midpoint attached to the second end of the stem portion, wherein the cross portion has a first end that extends in a curved manner from the midpoint and a second end that extends in a curved manner from the midpoint.

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